Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



OXENA FAMILY

Product types 2 and 4

(Active chlorine released from sodium hypochlorite as included in the Union list of approved active substances)

Case Number in R4BP: BC-QW045855-96

Evaluating Competent Authority: France

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# CONCLUSION

The biocidal products family, OXENA FAMILY, is based on 2.34 to 13.15 % of sodium hypochlorite (2.2 to 12.5 % of available chlorine), are product types 2 and 4 intended for disinfection. The products of this biocidal family are in the form of soluble concentrate, liquid or water based, to be applied for the disinfection against bacteria, fungi, yeast, virus, algae and lichens by industrial, professional and non-professional users depending of uses.

The BPF OXENA FAMILY is composed of 7 Meta-SPC:

* Meta-SPC 1– food industry
* Meta-SPC 2 – Bleach 9.6 - 12.5% professional
* Meta-SPC 3 – Bleach 2.6% professional
* Meta-SPC 4 – Bleach 2.6% non-professional
* Meta-SPC 5 – Anti-lichen professional
* Meta-SPC 6 – Bleach 4.8% non-professional
* Meta-SPC 7 – Thick Bleach professional

The biocidal product family OXENA FAMILY is claimed to be used for:

|  |  |  |
| --- | --- | --- |
| **PTs** | **Claimed uses** | **META SPC concerned** |
| 2 | Use # 1 – Disinfection of sanitary installations | 2, 3, 4, 6, 7 |
| 2 | Use # 2 – Disinfection of hard surfaces (non medical sector) by spraying, wiping, pouring, mopping or scrubbing | 2, 3, 4, 6, 7 |
| 2 | Use # 3 - Disinfection of hard surfaces (medical sector) by spraying, wiping, pouring, mopping or scrubbing | 2, 3 |
| 2 | Use # 4 – Anti-lichen and anti-algae treatment of hard surfaces | 5 |
| 4 | Use # 5 – Disinfection of hard surfaces in contact with food | 1, 2, 3, 4, 6, 7 |
| 2, 4 | Use # 6 – Disinfection of equipment/materials by spraying | 1, 2, 3 |
| 2, 4 | Use # 7 – Disinfection of equipment/materials by immersion/soaking | 2, 3 |
| 4 | Use # 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) | 1, 2, 3 |
| 4 | Use # 9– Disinfection of inner surfaces in veterinary water systems | 1, 2 |

Conclusions of the assessments of each section are given below:

**Conclusion of Physico chemical properties and analytical methods**

Physico chemical properties have been provided for representative products of each meta SPC and found acceptable*.*

Shelf lives can be set for meta SPC 1, 2, 3, 4, 6 and 7. Sodium chlorate content related to available chlorine is sometimes higher than 5.4% specification (refer to human health section regarding conclusion on chlorate content). When variations of active ingredient content after storage are higher than 10% of initial content, efficacy data was taken into account to support the shelf lives. **No shelf life can be granted for meta SPC 5 due to a lack of efficacy data. For Meta SPC 6, only the product Javel 4.8 GP Oxena has been tested and results cannot be extrapolated to other products of this meta SPC due to differences regarding compositions. Only a shelf life for Javel 4.8 GP Oxena can be granted.**

Some products form foam at a significant level (>60 mL after 1 min). Therefore, the mention “foaming products” is proposed. All products should be protected from light, stored at a temperature below 30°C and protected from frost.

Due to the nature of the active ingredient, products should not be used in conjunction with acids or ammonia. For products with a content of sodium hypochlorite higher than 5%, the mention EUH031 “contact with acids liberates toxic gas” is proposed. For products with a content of available chlorine higher than 1% w/w and proposed for non professional users, the mention EUH 206: “Warning! Do not use together with other products. May release dangerous gases (chlorine)” is proposed. All products are classified corrosive to metal H290 Met Corr. I. A DSC test and a study for oxidizing property on representative products of the BPF should be provided in post registration in order to confirm that products are not self reactive.

Analytical methods have been provided and are validated. **However, further validation data at a relevant limit of quantification for chlorate in the biocidal product family are required in post registration.**

**Conclusion of Efficacy**

The OXENA FAMILY has been shown to be efficacious for the products of the META-SPC1, META-SPC2, META-SPC3, META-SPC4 and META-SPC6. Nevertheless, for some uses, specific target organisms and validated application rates cannot be authorised. More information are detailed in the efficacy section and in the SPC.

For META-SPC7, no efficacy studies have been submitted for yeasts and efficacy studies performed on bacteria are not validated. Efficacy against bacteria and yeasts is a basic requirement for the PT2 and PT4 uses claimed, according to the Guidance on the BPR Vol.II part B/C, therefore efficacy for this META-SPC is not demonstrated.

For META-SPC5, the efficacy against algae and lichens for the treatment of hard surfaces is not demonstrated, therefore efficacy for this META-SPC is not demonstrated.

**Conclusion of risk characterisation for human health**

For the industrial and professional users:

* risks are acceptable for products of meta-SPC 2 and 3 for all the claimed uses, and products of meta-SPC 1, 5 and 7 for all the claimed uses except for the application with a compression sprayer, considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) and the condition to wear the personal protective equipment (PPE) listed in the SPC.
* For products of meta-SPC 1, 5 and 7, risk are not acceptable for the application with a compression sprayer considering the qualitative risk assessment for local effects.

For non-professional users:

* risks are acceptable for products of meta-SPC 4 and 6 for all the claimed uses except for the application by spraying, considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) listed in the SPC.
* For products of meta-SPC 4 and 6, risk are not acceptable for the application by spraying considering the qualitative risk assessment for local effects.

**Conclusion of risk for consumers via residues in food**

PT2 biocidal product are not intended for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

For PT4 uses, residues in food, feed or drink must be further investigated.

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly. Hence, residue formation (other than chlorate) is assumed to be negligible for aqueous solutions of chlorine. Conversely, chlorate residues, a stable metabolite that can be formed from hypochlorite sodium in aqueous chlorine solutions, are considered relevant for dietary exposure from the uses of active substance as food area disinfectant.

Regarding professional uses, considering the current knowledge about chlorate and the official chlorate limits in food, there is no concern for the general public from indirect exposure to either available chlorine or chlorate in food, feed and drinking water.

Considering the non-professional uses, a food contamination with chlorate via treated surface was estimated using maximalist scenario. No concern for general public from indirect exposure to either available chlorine or chlorate in food is observed when a rinsing of treated surfaces occurs.

**Conclusion of risk characterisation for environment**

Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance sodium hypochlorite leading to negligible emissions to the environment, considering a semi-qualitative assessment of chlorate for groundwater and surface water intended for the abstraction of drinking water and a quantitative assessment of the substance of concern: Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS n° 308062-28-4), for the uses 1, 2, 3, 5, 6, 7, 8 and 9

Unacceptable risks are foreseen for direct releases into the aquatic compartment considering a quantitative assessment of sodium hypochlorite for:

* PT2 use #4 Anti-lichen and anti-algae treatment of hard surfaces: Meta-SPC 5

The following risk mitigation measure should be applied to limit the direct emissions of product to the aquatic compartment

***Do not apply where the product can reach surface water.***

Note: Please note this use is not authorized due to unacceptable risks in HH section and the fact that efficacy has not been demonstrated. Therefore, the RMM is not relevant for this dossier.

***ED assessment***

An assessment of endocrine disruption (ED) properties of co-formulants in OXENA FAMILYhas been performed by FR CA.7 co-formulants show indications of endocrine activity (see confidential annex).

Based on available information, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case these co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

**General conclusion**

**Overall conclusions for the claimed uses**:

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family OXENA FAMILY is reported in the table below, for each use.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Uses** | **Meta-SPC** | **PT** | **Target organisms** | **Application rates**  **(in mg avCl/L)** | **Use conditions** | **Conclusions** |
| Use # 1 – Disinfection of sanitary installations | META-SPC 2 | 2 | Bacteria | 562 mg/L (clean)  4540 mg/L (dirty) | Professional  Non medical sector  Pouring  Indoor | **Acceptable** |
| Yeasts | 1513 mg/L (clean)  2270 mg/L (dirty) |
| Fungi (spores) | 2270 mg/L (clean)  6053 mg/L (dirty) |
| Bacteria  Yeasts | 1513 mg/L (clean) | Professional  Medical sector  Pouring.  Indoor | **Acceptable** |
| Fungi (spores) | 2270 mg/L (clean) |
| Bacteria | 2490 mg/L (dirty) | **Not acceptable : efficacy not demonstrated** |
| Yeasts | 1245 mg/L (dirty) |
| Fungi (spores) | 3320 mg/L (dirty) |
| META-SPC 3 | Bacteria | 403 mg/L (clean)  2149 mg/L (dirty) | Professional  Non medical sector  Pouring  Indoor | **Acceptable** |
| Yeasts | 274 mg/L (clean)  2106 mg/L (dirty) |
| Fungi (spores) | 1368 mg/L (clean)  4842 mg/L (dirty) |
| Bacteria  Yeasts | 547 mg/L (clean) | Professional  Medical sector  Pouring.  Indoor | **Acceptable** |
| Fungi (spores) | 1368 mg/L (clean) |
| Bacteria | 2080 mg/L (dirty) | **Not acceptable : efficacy not demonstrated** |
| Yeasts | 2000 mg/L (dirty) |
| Fungi (spores) | 4600 mg/L (dirty) |
| META-SPC 4 | Bacteria | 403 mg/L (clean)  1881 mg/L (dirty) | Non professional  Non medical sector  Pouring  Indoor | **Acceptable** |
| Yeasts | 269 mg/L (clean)  1075 mg/L (dirty) |
| Fungi (spores) | 1075 mg/L (clean)  2149 mg/L (dirty) |
| Bacteria  Yeasts | 403 mg/L (clean) | Non professional  Medical sector  Pouring.  Indoor | **Acceptable** |
| Fungi (spores) | 1075 mg/L (clean) |
| Bacteria | 1820 mg/L (dirty) | **Not acceptable : efficacy not demonstrated** |
| Yeasts | 1040 mg/L (dirty) |
| Fungi (spores) | 2080 mg/L (dirty) |
| META-SPC 6 | Bacteria | 413 mg/L (clean)  1961 mg/L (dirty) | Non professional  Non medical sector  Pouring  Indoor | **Acceptable** |
| Yeasts | 269 mg/L (clean)  1135 mg/L (dirty) |
| Fungi (spores) | 1075 mg/L (clean)  2270 mg/L (dirty) |
| Bacteria  Yeasts | 413 mg/L (clean) | Non professional  Medical sector  Pouring.  Indoor | **Acceptable** |
| Fungi (spores) | 1135 mg/L (clean) |
| Bacteria | 1820 mg/L (dirty) | **Not acceptable : efficacy not demonstrated** |
| Yeasts | 1040 mg/L (dirty) |
| Fungi (spores) | 2080 mg/L (dirty) |
| META-SPC 2, 3, 4, 6 | 2 | Virus | 2080 mg/L (dirty) | Professional & non professional  Medical & non-medical sector  Pouring.  Indoor | **Not acceptable : efficacy not demonstrated** |
| META-SPC 7 | Bacteria  Fungi (spores) | 1610 mg/L (dirty) | Professional  Medical & non-medical sector  Pouring.  Indoor | **Not acceptable : efficacy not demonstrated** |
| Use # 2 – Disinfection of hard surfaces (non medical sector) by spraying, wiping, pouring, mopping or scrubbing | META-SPC 2 | 2 | Bacteria | 562 mg/L (clean)  4540 mg/L (dirty) | Professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Acceptable** |
| Yeasts | 1513 mg/L (clean)  2270 mg/L (dirty) |
| Fungi (spores) | 2270 mg/L (clean)  6053 mg/L (dirty) |
| META-SPC 3 | Bacteria | 547 mg/L (clean)  2188 mg/L (dirty) | **Acceptable** |
| Yeasts | 274 mg/L (clean)  1094 mg/L (dirty) |
| Fungi (spores) | 1368 mg/L (clean)  2462 mg/L (dirty) |
| META-SPC 4 | Bacteria | 403 mg/L (clean)  1881 mg/L (dirty) | Non professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Not acceptable:**  **Foreseen risks for human health with spraying application of the product.** |
| Yeasts | 269 mg/L (clean)  1075 mg/L (dirty) |
| Fungi (spores) | 1075 mg/L (clean)  2149 mg/L (dirty) |
| META-SPC 6 | Bacteria | 413 mg/L (clean)  1961 mg/L (dirty) |
| Yeasts | 269 mg/L (clean)  1075 mg/L (dirty) |
| Fungi (spores) | 1135 mg/L (clean)  2270 mg/L (dirty) |
| META-SPC 4 | Bacteria | 403 mg/L (clean)  1881 mg/L (dirty) | Non professional  Wiping, pouring, mopping and scrubbing.  Indoor | **Acceptable** |
| Yeasts | 269 mg/L (clean)  1075 mg/L (dirty) |
| Fungi (spores) | 1075 mg/L (clean)  2149 mg/L (dirty) |
| META-SPC 6 | Bacteria | 413 mg/L (clean)  1961 mg/L (dirty) | **Acceptable** |
| Yeasts | 269 mg/L (clean)  1075 mg/L (dirty) |
| Fungi (spores) | 1135 mg/L (clean)  2270 mg/L (dirty) |
| META-SPC 2, 3, 4, 6 | 2 | Virus | 2080 mg/L (dirty) | Professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Not acceptable : efficacy not demonstrated** |
| META-SPC 7 | Bacteria  Fungi (spores) | 1610 mg/L (dirty) | Professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Not acceptable : efficacy not demonstrated and foreseen risks for human health with spraying application of the product as well as application with mop/brush without handle** |
| Use # 3 - Disinfection of hard surfaces (medical sector) by spraying, wiping, pouring, mopping or scrubbing | META-SPC 2 | 2 | Bacteria  Yeasts | 1513 mg/L (clean) | Professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Acceptable** |
| Fungi (spores) | 2270 mg/L (clean) |
| META-SPC 3 | Bacteria  Yeasts | 547 mg/L (clean) |
| Fungi (spores) | 1368 mg/L (clean) |
| META-SPC 2, 3 | Virus | 3120 mg/L (dirty) | **Not acceptable : efficacy not demonstrated** |
| Bacteria | 2080mg/L (dirty) |
| Yeasts | 4600mg/L (dirty) |
| Fungi (spores) | 2000mg/L (dirty) |
| Use # 4 – Anti-lichen and anti-algae treatment of hard surfaces | META-SPC 5 | 2 | Algae & lichen | 1 treatment per year maximum at0.1 L/m2 | Professional  Spraying  Outdoor | **Not acceptable : efficacy not demonstrated and foreseen risks for human health with spraying application of the product.** |
| Use # 5 – Disinfection of hard surfaces in contact with food | META SPC 1 | 4 | Bacteria  Yeasts | 573 mg/L (clean)  4287 mg/L (dirty) | Professional, and industrial (meta-SPC 1 only)  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Unacceptable:**  **Foreseen risks for human health with spraying (compression and venture) application of the product as well as application with mop and brush without handle.** |
| Fungi (spores) | 2144 mg/L (clean)  3572 mg/L (dirty) |
| META-SPC 1 | Bacteria  Yeasts | 573 mg/L (clean)  4287 mg/L (dirty) | Professional, and industrial (meta-SPC 1 only)  Spraying (only with trigger spray), Wiping, pouring, mopping and scrubbing with a mop or a brush with handle.  Indoor | **Acceptable** |
| Fungi (spores) | 2144 mg/L (clean)  3572 mg/L (dirty) |
| META-SPC 2 | Bacteria  Yeasts | 1513 mg/L (clean)  4540 mg/L (dirty) | Professional, and industrial (meta-SPC 1 only)  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Acceptable** |
| Fungi (spores) | 2270 mg/L (clean)  6053 mg/L (dirty) |
| META-SPC 3 | Bacteria  Yeasts | 547 mg/L (clean)  2188 mg/L (dirty) | **Acceptable** |
| Fungi (spores) | 1368 mg/L (clean)  4842 mg/L (dirty) |
| META SPC 4 | Bacteria  Yeasts | 403 mg/L (clean)  1881 mg/L (dirty) | Non Professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Unacceptable:**  **Foreseen risks for human health with spraying application of the product.** |
| Fungi (spores) | 1075 mg/L (clean)  2149 mg/L (dirty) |
| META SCP 6 | Bacteria  Yeasts | 413 mg/L (clean)  1961 mg/L (dirty) |
| Fungi (spores) | 1135 mg/L (clean)  2270 mg/L (dirty) |
| META-SPC 4 | Bacteria  Yeasts | 403 mg/L (clean)  1881 mg/L (dirty) | Non Professional Wiping, pouring, mopping and scrubbing.  Indoor | **Acceptable** |
| Fungi (spores) | 1075 mg/L (clean)  2149 mg/L (dirty) |
| META-SPC 6 | Bacteria  Yeasts | 413 mg/L (clean)  1961 mg/L (dirty) | **Acceptable** |
| Fungi (spores) | 1135 mg/L (clean)  2270 mg/L (dirty) |
| META-SPC 2, 3, 4, 6 | Virus | 2080 mg/L (dirty) | Professional & non professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Not acceptable : efficacy not demonstrated** |
| META-SPC 7 | 4 | Bacteria  Fungi (spores) | 1610 mg/L (dirty) | Professional  Spraying, wiping, pouring, mopping and scrubbing.  Indoor | **Not acceptable : efficacy not demonstrated**  **and unacceptable risks for human health with spraying application of the product as well as application with mop and brush without handle.** |
| Use # 6 – Disinfection of equipment/  materials by spraying | META-SPC 1 | 2, 4 | Bacteria  Fungi (spores)  Yeasts | Clean condition :  Bacterias : 275 mg/L  Fungi (spores) : 1650 mg/L  Yeasts: 400 mg/L  Dirty condition:  Bacterias : 3300 mg/L  Fungi (spores) : 2750 mg/L  Yeasts : 1200 mg/L | Professional and industrial  Spraying  Indoor | **Not acceptable : efficacy not demonstrated** |
| META-SPC 2 | Bacteria  Fungi (spores)  Yeasts  Virus | Clean condition :  Bacterias : 470 mg/L  Fungi (spores) : 1245mg/L  Yeasts : 830 mg/L  Dirty condition:  Bacterias : 2490 mg/L  Fungi (spores) : 3320 mg/L  Yeasts : 1245 mg/L  Virus : 2080 mg/L | Professional  Spraying  Indoor | **Not acceptable : efficacy not demonstrated** |
| META-SPC 3 | Bacteria  Fungi (spores)  Yeasts  Virus | Clean condition :  Bacterias : 390 mg/L  Fungi (spores) : 1040 mg/L  Yeasts : 260 mg/L  Dirty condition :  Bacterias : 2080 mg/L  Fungi(spores) : 4600 mg/L  Yeasts : 2000 mg/L  Virus : 2080 mg/L | **Not acceptable : efficacy not demonstrated** |
| Use # 7 – Disinfection of equipment/  materials by immersion/  soaking | META-SPC 2 | 2 | Bacteria | 562 mg/L (clean)  4540 mg/L (dirty) | Professional  Non medical sector  Immersion/soaking  Indoor | **Acceptable** |
| Yeasts | 1513 mg/L (clean)  2270 mg/L (dirty) |
| Fungi (spores) | 2270 mg/L (clean)  6053 mg/L (dirty) |
| 4 | Bacteria  Yeasts | 1513 mg/L (clean)  4540 mg/L (dirty) | Professional  Food and feed area  Immersion/soaking  Indoor | **Acceptable** |
| Fungi (spores) | 2270 mg/L (clean)  6053 mg/L (dirty) |
| META-SPC 3 | 2 | Bacteria | 547 mg/L (clean)  2188 mg/L (dirty) | Professional  Non medical sector  Immersion/soaking  Indoor | **Acceptable** |
| Yeasts | 274 mg/L (clean)  2106 mg/L (dirty) |
| Fungi (spores) | 1368 mg/L (clean)  4842 mg/L (dirty) |
| 4 | Bacteria  Yeasts | 547 mg/L (clean)  2188 mg/L (dirty) | Professional  Food and feed area  Immersion/soaking  Indoor | **Acceptable** |
| Fungi (spores) | 1368 mg/L (clean)  4842 mg/L (dirty) |
| META-SPC 2, 3 | 2, 4 | Virus | 2080 mg/L (dirty) | Professional  Immersion/soaking  Indoor | **Not acceptable : efficacy not demonstrated** |
| Use # 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) | META-SPC 1 | 4 | Bacteria  Yeasts | 500 mg/L (clean)  3779 mg/L (dirty) | Professional and industrial  Cleaning-in-place (CIP)  Indoor | **Acceptable**  **Not acceptable in dirty condition**  **for milk and dairy production: efficacy not demonstrated** |
| Fungi (spores) | 2144 mg/L (clean)  3149 mg/L (dirty) |
| META-SPC 2 | Bacteria  Yeast | 1059 mg/L (clean)  3027 mg/L (dirty) | Professional  Food and feed area  Cleaning-in-place (CIP)  Indoor | **Acceptable**  **Not acceptable in dirty condition**  **for milk and dairy production: efficacy not demonstrated** |
| Fungi (spores) | 2270 mg/L (clean)  4540 mg/L (dirty) |
| META-SPC 3 | Bacteria  Yeasts | 410 mg/L (clean)  2188 mg/L (dirty) | Professional  Food and feed area  Cleaning-in-place (CIP)  Indoor | **Acceptable**  **Not acceptable in dirty condition**  **for milk and dairy production: efficacy not demonstrated** |
| Fungi (spores) | 1094 mg/L (clean)  4842 mg/L (dirty) |
| META-SPC 2, 3 | 4 | Virus | 2080 mg/L (dirty) | Professional  Food and feed area  Cleaning-in-place (CIP)  Indoor | **Not acceptable : efficacy not demonstrated** |
| Use # 9– Disinfection of inner surfaces in veterinary water systems | META-SPC 1 | 4 | Bacteria | 500 mg/L (clean)  4287 mg/L (dirty) | Professional and industrial  Food and feed area  Pouring  Indoor | **Acceptable** |
| Yeasts | 458 mg/L (clean)  1718 mg/L (dirty) |
| Fungi (spores) | 2144 mg/L (clean)  3572 mg/L (dirty) |
| META-SPC 2 | Bacteria | 562 mg/L (clean)  4540 mg/L (dirty) | Professional  Food and feed area  Pouring  Indoor | **Acceptable** |
| Yeasts | 1059 mg/L (clean)  1513 mg/L (dirty) |
| Fungi (spores) | 2270 mg/L (clean)  4540 mg/L (dirty) |
| META-SPC 1, 2 | Virus | 2080 mg/L (dirty) | Professional and industrial  Food and feed area  Pouring  Indoor | **Not acceptable : efficacy not demonstrated** |

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-2)** | **France** |
| --- | --- |
|  | Mutual Recognition in parallel in the following countries:  Spain, Portugal, Romania, Poland, Hungary, Bulgaria, Czech Republic, Switzerland, Ireland, Luxembourg |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Laboratoire OXENA |
| **Address** | ZI LA MOTTE SUD  Rue Marc Seguin  26800 PORTES LES VALENCE  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Laboratoire OXENA |
| **Address of manufacturer** | ZI LA MOTTE SUD  Rue Marc Seguin  26800 PORTES LES VALENCE  France |
| **Location of manufacturing sites** | ZI LA MOTTE SUD  Rue Marc Seguin  26800 PORTES LES VALENCE  France |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Sodium hypochlorite |
| **Name of manufacturer** | ARKEMA |
| **Address of manufacturer** | 420 rue d’Estienne d’Orves  92705 Colombes Cedex  France |
| **Location of manufacturing sites** | USINE DE JARRIE  Route Nationale 85  38560 Jarrie – France |
|  |  |
| **Active substance** | Sodium hypochlorite |
| **Name of manufacturer** | INOVYN Trade Services SA (Acting for INOVYN Chlorvinyls Limited (UK)) |
| **Address of manufacturer** | South Parade, Runcorn  Cheshire WA7 4JE |
| **Location of manufacturing sites** | INOVYN France SAS  2 Avenue de la République  CS 10001  39501 Tavaux Cedex – FRANCE |
|  |  |
| **Active substance** | Sodium hypochlorite |
| **Name of manufacturer** | Kem One |
| **Address of manufacturer** | 19 rue Jacqueline Auriol  Bât A  Le Quadrille  69008 Lyon  France |
| **Location of manufacturing sites** | Usine de Lavéra  Écopolis Lavéra-Sud - BP 3  13117 Lavéra – France  Usine de Saint Fons  1 quai Louis Aulagne  69191 SAINT-FONS – France |
|  |  |

### Product family composition and formulation

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | **-** |
| **IUPAC or EC name** | Sodium hypochlorite |
| **EC number** | 231-668-3 |
| **CAS number** | 7681-52-9 |
| **Index number in Annex VI of CLP** | ATP 13 (Reg (UE) 2018/1480): 017-011-00-1  Enter in force in 1st May 2020 |
| **Minimum purity / content** | Minimum purity of the releaser sodium hypochlorite: aqueous solution with an active chlorine concentration ≤ 180 g/kg (i.e. ≤ 18 % w/w).  One relevant impurity is present: sodium chlorate (≤5.4% of the active chlorine, meaning 0.12 - 0.675% w/w in the biocidal product family) |
| **Structural formula** | Na+ Cl – O |

#### Candidate(s) for substitution

#### Sodium hypochlorite does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. Qualitative and quantitative information on the composition of the biocidal product family2

#### Details on compositions of each meta SPC and related products are reported in the confidential annex.

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 | 12.5 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6 to 14.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 | 86.2 |
| Sodium hydoxide | Sodium hydroxide | Stabilizer | 1310-73-2 | 215-185-5 | 0 | 6.14 |
| Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | Surfactant | 308062-28-4 | 931-292-6 | 0 | 8 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical concentrate is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the purity of NaOCl in TK is ranging from 96 to 145g/kg.

#### Information on technical equivalence

The origins Arkema and Inovyn used are recognized at EU level according to Article 95. Plant locations are also identical to the ones mentioned in the CAR of the active substance (PT2) and complying with the reference specifications.

For Kem One origins, Technical equivalences have been performed by Echa and found acceptable.

The minimum purity set for reference sources in the CAR is as follow:

“aqueous solution with an active chlorine concentration ≤180g/kg. Sodium chlorate is a relevant impurity and should not exceed 5.4% of the active chlorine”. The third origin (Kem One) has been assessed during technical equivalence prepared by Echa and reports are available on Circa for both plant locations.

#### Information on the substance(s) of concern

Please see the confidential annex for further details.

Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides and sodium hydroxide have been identified as substances of concern in the biocidal product family.

Please note that sodium chlorate has been identified as a relevant impurity in technical material (max content: 5.4% of active chlorine content, meaning 0.12 - 0.675% w/w in the biocidal product family).

#### Assessment of endocrine disruption (ED) properties of the biocidal product family

According to our assessment, none of the co-formulants contained in the products of the OXENA FAMILY are regulatory identified as endocrine disruptors.

However, based on screening, 7 co-formulants show indications of endocrine activity and this should be further assessed in the frame of REACH Regulation.

One of these co-formulants are currently being evaluated in the frame of REACH Regulation for its potential ED properties.

Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product family will be considered as ED and authorisation will have to be revised accordingly.

Please refer to Confidential Annex.

#### Type of formulation

|  |
| --- |
| SL: soluble concentrate, liquid, water based |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1 – Food industry |
| --- | --- |

#### Suffix to the authorisation number

| 1 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 4 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 5.0 | 6.3 |
| Sodium hypochlorite (technical solution with minimum purity of  12.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 40.0 | 50.4 |
| Sodium hydoxide | Sodium hydroxide | Stabilizer | 1310-73-2 | 215-185-5 | 6 | 6.14 |
| Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | Surfactant | 308062-28-4 | 931-292-6 | 0 | 8 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical concentrate is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the purity of NaOCl in TK is ranging from 96 to 145g/kg.

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| SL – soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr. 1  Eye Dam. 1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe ski burns  H318: Causes serious eye damage  H400: Very toxic to aquatic life.  H411: Toxic to aquatic life with long-lasting effects. |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| Signal words | GHS05 Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long lasting effect. |
| Precautionary statements | P260: Do not breathe dust/fume/gas/mist/vapours/spray.  P264: Wash … thoroughly after handling.  P273: Avoid released to the environment  P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hait): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.  P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310. Immediately call a POISON CENTER or doctor/physician  P321: Specfic treatment (see … on the label).  P363: Wash contaminated clothing before reuse.  P391: Collect spillage  P405: Store locked up.  P501: Dispose of contents/container in accordance with the national regulation |
| Suppl. hazard statement |  |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071: Corrosive to the respiratory tract. |

### Authorised use(s) of the META SPC 1

#### Use description[[2]](#footnote-3)

Table 1. Use # 5 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying (only with trigger spray), mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Contact time: 15 min  Clean conditions:  Bacteria, yeasts (obligatory): 573 mg/L a.c  Bacteria, yeasts and fungi (optional): 2144 mg/L a.c  Dirty conditions:  Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c |
| **Category(ies) of users** | Industrial and professional |
| **Pack sizes and packaging material** | HDPE can 5L, 10L, 20L, 25L, 30L  HDPE barrel 5L, 10L, 20L, 30L, 60L, 200L  HDPE drum 5L, 20L  HDPE bottle 5L  HDPE keg 60L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 15 minutes, then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application with a trigger spray and rinsing, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and only for application a respiratory protective equipment against aerosols * For application by mopping/scrubbing and rinsing with a mop:   - wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles  - A mop/brush with handle has to be used to apply the diluted solution to avoid exposure  - Do not immerse hands in the diluted solution   * For application by wiping and rinsing:   - wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles  - pour the solution directly on the surface and wipe with a cloth   * For application by pouring and rinsing   - wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles,  - avoid direct contact with the solution to be applied   * For professional bystander: Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user. * For general public:   - Do not be present in the treatment area during disinfection process by trigger spray.  - Do not touch the surface until it is rinsed and totally dried  - Children should not be present during disinfection and until the surface is rinsed and dry   * Animals should not be present during disinfection and until the surface is rinsed and dry |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 2. Use # 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP)

|  |  |
| --- | --- |
| **Product Type** | **PT4** |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas by circulation (CIP) |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Cleaning In Place by circulation |
| **Application rate(s) and frequency** | Contact time: 15 min  Clean conditions:  Bacteria, yeasts (obligatory): 500 mg/L a.c  Bacteria, yeasts and fungi (optional): 2144 mg/L a.c  Dirty conditions (except milk and dairy production and milking parlour systems):  Bacteria, yeasts (obligatory) and fungi: 3779 mg/L a.c |
| **Category(ies) of users** | Industrial and professional |
| **Pack sizes and packaging material** | HDPE can 5L, 10L, 20L, 25L, 30L  HDPE barrel 5L, 10L, 20L, 30L, 60L, 200L  HDPE drum 5L, 20L  HDPE bottle 5L  HDPE keg 60L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for applications in milk and dairy production and milking parlour systems. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For maintenance of circuit system, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles * For maintenance of dosing pumps, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and respiratory protective equipment against aerosols |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 4. Use # 9 – Disinfection of inner hard surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | **PT4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | Clean conditions:  Bacteria (obligatory): 500 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 500 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2144 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 4287 mg/L a.c, contact time: 5 min  Bacteria, yeasts and fungi (optional): 4282 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Industrial and professional |
| **Pack sizes and packaging material** | HDPE can 5L, 10L, 20L, 25L, 30L  HDPE barrel 5L, 10L, 20L, 30L, 60L, 200L  HDPE drum 5L, 20L  HDPE bottle 5L  HDPE keg 60L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For maintenance of circuit system, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles * For maintenance of dosing pumps, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and respiratory protective equipment against aerosols |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 1

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia * Comply with the instructions for use * Apply only on non-porous surfaces |

#### Risk mitigation measures

|  |
| --- |
| * For mixing and loading task, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles * Rinse surfaces after treatment |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.   If symptoms: Call 112/ambulance for medical assistance.  If no symptoms: Call a POISON CENTRE or a doctor.   * IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse.   Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.   * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.   Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid   * IF SWALLOWED:   Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| * Shelf life: 5 months. * Protect from frost. * Protect from direct sunlight. * Do not store above 30°C. |

### Other information

|  |
| --- |
| * Foaming products * The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. * The applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the OXENA FAMILY family. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Oxe Alca  BACTI A NON MOUSSANT | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 6.3 |
| Sodium hypochlorite (technical solution with minimum purity of  12.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 50.4 |
| Sodium hydroxide | Sodium hydroxide | stabilizer | 7681-52-9 |  | 6.14 |
| Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | surfactant | 308062-28-4 | 931-292-6 | 0 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Oxe Alca chlore moussant  BACTI A MOUSSANT | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 5.0 |
| Sodium hypochlorite (technical solution with minimum purity of  12.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 40.0 |
| Sodium hydroxide | Sodium hydroxide | stabilizer | 7681-52-9 |  | 6 |
| Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides | surfactant | 308062-28-4 | 931-292-6 | 8 |

**Part II - Second information level - meta SPC 2**

### Meta SPC 2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 2 – Bleach 9.6 – 12.5% professional |
| --- | --- |

#### Suffix to the authorisation number

| 2 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2, 4 |
| --- | --- |

### Meta SPC 2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 9.6 | 12.5 |
| Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 66.2 | 86.2 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical concentrate is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the purity of NaOCl in TK concentrate is ranging from 96 to 145g/kg.

#### Type(s) of formulation of the meta SPC 2

|  |
| --- |
| SL – soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Corr. 1  Eye Dam. 1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H314: Causes severe skin burns  H318: Causes serious eye damage  H400: Very toxic to aquatic life.  H411: Toxic to aquatic life with long-lasting effects. |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| Signal words | GHS05 Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H314: Causes severe skin burns and eye damage  H410: Very toxic to aquatic life with long lasting effect. |
| Precautionary statements | P260: Do not breathe dust/fume/gas/mist/vapours/spray.  P264: Wash … thoroughly after handling.  P273: Avoid released to the environment  P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.  P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303+P361+P353: IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/shower.  P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor/physician  P321: Specific treatment (see … on this label).  P363: Wash contaminated clothing before reuse.  P391: Collect spillage  P405: Store locked up  P501: Dispose of contents/container in accordance with the national regulation |
| Suppl. hazard statement |  |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas  EUH071: Corrosive to the respiratory tract. |

### Authorised use(s) of the META SPC 2

#### Use description[[3]](#footnote-4)

Table 5. Use # 1 – Disinfection of sanitary installations

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Medical sector  Non medical sector |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | **Non medical sector:**  Clean conditions:  Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min  **Medical sector:**  Clean conditions:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 1513 mg/L a.c,  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 6. Use # 2 – Disinfection of hard surfaces (non medical sector)

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Non medical sector |
| **Application method(s)** | Spraying, mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Clean carefully the surfaces before application of the product for application in clean conditions. * Allow to take effect for at least 5 or 15 minutes (depending on the target organism), then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF4. * For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user * For general public: Do not be present in the treatment area during disinfection process by compression sprayer   Animals should not be present in the treatment area during disinfection process by compression sprayer.   * Avoid any direct or indirect contact with food. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 7. Use # 3 – Disinfection of hard surfaces (medical sector)

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Medical sector |
| **Application method(s)** | Spraying, mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Contact time: 15 min  Bacteria (obligatory) and yeasts : 1513 mg/L a.c.  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 15 minutes (depending on the target organism), then mop/wipe/scrub if required. * For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF4. * For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user * For general public: Do not be present in the treatment area during disinfection process by compression sprayer * Animals should not be present in the treatment area during disinfection process by compression sprayer * Avoid any direct or indirect contact with food. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 8. Use # 5 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying, mopping, pouring, wiping, scrub (no mechanical action) |
| **Application rate(s) and frequency** | Contact time: 15 min  Clean conditions:  Bacteria, yeasts (obligatory): 1513 mg/L a.c  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c  Dirty conditions:  Bacteria, yeasts (obligatory): 4540 mg/L a.c  Bacteria, yeasts and fungi (optional): 6053 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Clean carefully the surfaces before application of the product for application in clean conditions. * Allow to take effect for at least 15 minutes, then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application and rinsing with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF4. * For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user * For general public: Do not be present in the treatment area during disinfection process by compression sprayer * Animals should not be present in the treatment area during disinfection process by compression sprayer * Rinse surfaces after treatment. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 10. Use # 7 – Dinsinfection of equipment/materials by immersion/soaking

|  |  |
| --- | --- |
| **Product Type** | **PT 4 and PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Non medical sector (PT2)  Food and feeding industry (PT4) |
| **Application method(s)** | Immersion/soaking |
| **Application rate(s) and frequency** | **Non medical sector (PT2):**  Clean conditions:  Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min  **Food and feeding industry (PT 4):**  Clean conditions:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 1513 mg/L a.c,  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c  Dirty conditions:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 4540 mg/L a.c,  Bacteria, yeasts and fungi (optional): 6053 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 11. Use # 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP)

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas by circulation (CIP) |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Cleaning In Place by circulation |
| **Application rate(s) and frequency** | Contact time: 15 min  Clean conditions:  Bacteria, yeast (obligatory): 1059 mg/L a.c  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c  Dirty conditions (except milk and dairy production and milking parlour systems):  Bacteria, yeast (obligatory): 3027 mg/L a.c  Bacteria, yeasts and fungi (optional): 4540 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment. * For maintenance of dosing pumps, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and respiratory protective equipment against aerosols |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

#### Use description

Table 4. Use # 9 – Disinfection of inner hard surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | **PT4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | Clean conditions:  Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1059 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min  Bacteria, Yeasts and fungi (optional): 4540 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | HDPE bottle 250 mL  HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L  HDPE barrels 5L, 10L, 20L, 30L, 60L  HDPE drum 2L, 5L, 10L, 20L, 30L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For maintenance of dosing pumps, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and respiratory protective equipment against aerosols |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
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|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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|  |

### General directions for use of the meta SPC 2

#### Instructions for use

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| --- |
| * Products should not be used in conjunction with acids or ammonia * Comply with the instructions for use * Apply only on non-porous surfaces |

#### Risk mitigation measures

|  |
| --- |
| * For mixing and loading task, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.   If symptoms: Call 112/ambulance for medical assistance.  If no symptoms: Call a POISON CENTRE or a doctor.   * IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse.   Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.   * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.   Call 112/ambulance for medical assistance.  Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid   * IF SWALLOWED: * Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| * Shelf life: 5 months * Protect from frost. * Protect from direct sunlight. * Do not store above 30°C. |

### Other information

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| --- |
| * The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. * The applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the OXENA FAMILY family. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 9.6 pro Oxena  SODICLEAN  EXTRAIT DE JAVEL LE GLOBE  JAVEL 9,6% DISTRICONCEPT  Javel Gros Travaux Starco | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 9.6 |
| Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 66.2 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 12.5 pro Oxena  SODICLEAN SODIF  SODICLEAN PREMIUM  EAU DE JAVEL CONCENTRE LE GLOBE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 12.5 |
| Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 86.2 |

**Part II - Second information level - meta SPC 3**

### Meta SPC 3 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 3 – Bleach 2.6% professional |
| --- | --- |

#### Suffix to the authorisation number

| 3 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2, 4 |
| --- | --- |

### Meta SPC 3 composition

#### Qualitative and quantitative information on the composition of the meta SPC 3

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 | 27.1 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical concentrate is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the purity of NaOCl in TK concentrate is ranging from 96 to 145g/kg.

#### Type(s) of formulation of the meta SPC 3

|  |
| --- |
| SL – soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Irri. 2  Eye Dam. 1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H315: Causes skin irritation  H318: Causes serious eye damage  H400: Very toxic to aquatic life.  H411: Toxic to aquatic life with long-lasting effects. |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| Signal words | GHS05 Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H315: Causes skin irritation  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effect. |
| Precautionary statements | P264: Wash … thoroughly after handling.  P273: Avoid released to the environment  P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.  P302+P352: IF ON SKIN: Wash with plenty of soap and water.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor/physician  P321: Specific treatment (see … on this label).  P332+P313: If skin irritation occurs: Get medical advice/attention.  P362+P364: Take off contaminated clothing and wash before reuse.  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
| Suppl. hazard statement |  |
|  | |
| Note |  |

### Authorised use(s) of the META SPC 3

#### Use description[[4]](#footnote-5)

Table 12. Use # 1 – Disinfection of sanitary installations

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Medical sector  Non medical sector |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | **Non medical sector:**  Clean conditions:  Bacteria (obligatory): 403 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 403 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 2149 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 2149 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 4842 mg/L a.c, contact time: 15 min  **Medical sector:**  Clean conditions only:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 547 mg/L a.c,  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 10L, 20L, 25L, 30L  HDPE drum 1L, 2L, 5L, 10L, 20L, 30L  HDPE bottle 1L, 2L, 5L  HDPE keg 60L  HDPE barrel 5L, 10L, 20L, 30L, 200L  HDPE IBC 1000L |

#### Use-specific instructions for use[[5]](#footnote-6)

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food. * For application by pouring, wear chemical goggles |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 13. Use # 2 – Disinfection of hard surfaces (non medical sector)

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Non medical sector |
| **Application method(s)** | Spraying, mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Bacteria (obligatory): 547 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 547 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 2188 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 2188 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2462 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 10L, 20L, 25L, 30L  HDPE drum 1L, 2L, 5L, 10L, 20L, 30L  HDPE bottle 1L, 2L, 5L  HDPE keg 60L  HDPE barrel 5L, 10L, 20L, 30L, 200L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 5 or 15 minutes (depending on the target organism), then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application with a compression sprayer, wear chemical goggles and respiratory protective equipment against aerosols at minima APF4. * For application by spraying with a trigger spray, by mopping, wiping, scrubbing and pouring, wear chemical goggles * For professional bystander:   - Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user  - Do not touch the surface until it is completely dried   * For general public:   - Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray  - Do not touch the surface until it is rinsed and completely dried  - Children should not be present during disinfection and until the surface is rinsed and dry   * Animals should not be present during disinfection and until the surface is rinsed and dry * avoid any direct or indirect contact with food |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
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|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 14. Use # 3 – Disinfection of hard surfaces (medical sector)

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Medical sector |
| **Application method(s)** | Spraying, mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Contact time: 15 min  Bacteria (obligatory) and yeasts : 547 mg/L a.c  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 10L, 20L, 25L, 30L  HDPE drum 1L, 2L, 5L, 10L, 20L, 30L  HDPE bottle 1L, 2L, 5L  HDPE keg 60L  HDPE barrel 5L, 10L, 20L, 30L, 200L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 15 minutes, then mop/wipe/scrub if required. * For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application with a compression sprayer, wear chemical goggles and respiratory protective equipment against aerosols at minima APF4. * For application by spraying with a trigger spray, by mopping, wiping, scrubbing and pouring, wear chemical goggles * For professional bystander:   - Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user  - Do not touch the surface until it is completely dried   * For general public   - Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray  - Do not touch the surface until it is rinsed and completely dried  - Children should not be present during disinfection and until the surface is rinsed and dry   * Animals should not be present during disinfection and until the surface is rinsed and dry * Avoid any direct or indirect contact with food. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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#### Use description

Table 15. Use # 5 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying, mopping, pouring, wiping , scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Contact time: 15 min  Bacteria, yeasts (obligatory): 547 mg/L a.c  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c  Dirty conditions:  Bacteria, yeasts (obligatory): 2188 mg/L a.c, contact time: 5 min  Bacteria, yeasts and fungi (optional): 4842 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 10L, 20L, 25L, 30L  HDPE drum 1L, 2L, 5L, 10L, 20L, 30L  HDPE bottle 1L, 2L, 5L  HDPE keg 60L  HDPE barrel 5L, 10L, 20L, 30L, 200L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 5 or 15 minutes (depending on the target organism and the soiling condition), then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For application and rinsing with a compression sprayer, wear chemical goggles and respiratory protective equipment at minima APF4. * For application by spraying with a trigger spray, by mopping, wiping, scrubbing and pouring and rinsing, wear chemical goggles * For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user * For general public:   - Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray.  - Do not touch the surface until it is rinsed and completely dried  - Children should not be present during disinfection and until the surface is rinsed and dry   * Animals should not be present during disinfection and until the surface is rinsed and dry * Rinse surfaces after treatment. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
|  |

#### Use description

Table 17. Use # 7 – Dinsinfection of equipment/materials by immersion/soaking

|  |  |
| --- | --- |
| **Product Type** | **PT 4 and PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Non medical sector (PT2)  Food and feeding industry (PT4) |
| **Application method(s)** | Immersion/soaking |
| **Application rate(s) and frequency** | **Non medical sector (PT 2):**  Clean conditions:  Bacteria (obligatory): 547 mg/L a.c, contact time: 5 min  Bacteria, yeasts (optional): 547 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 2188 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 2188 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 4842 mg/L a.c, contact time: 15 min  **Food and feeding industry (PT 4):**  Clean conditions:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 547 mg/L a.c,  Bacteria, yeasts and fungi (optional): 1368 mg/L a.c  Dirty conditions:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 2188 mg/L a.c,  Bacteria, yeasts and fungi (optional): 4842 mg/L a.c |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 10L, 20L, 25L, 30L  HDPE drum 1L, 2L, 5L, 10L, 20L, 30L  HDPE bottle 1L, 2L, 5L  HDPE keg 60L  HDPE barrel 5L, 10L, 20L, 30L, 200L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * For application by immersion, wear chemical goggles |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 18. Use # 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP)

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas by circulation (CIP) |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Cleaning In Place by circulation |
| **Application rate(s) and frequency** | Clean conditions:  Contact time: 15 min  Bacteria, yeasts (obligatory): 410 mg/L a.c  Bacteria, yeasts and fungi (optional): 1094 mg/L a.c  Dirty conditions (except milk and dairy production and milking parlour systems):  Bacteria, yeasts (obligatory): 2188 mg/L a.c, contact time: 5 min  Bacteria, yeasts and fungi (optional): 4842 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 10L, 20L, 25L, 30L  HDPE drum 1L, 2L, 5L, 10L, 20L, 30L  HDPE bottle 1L, 2L, 5L  HDPE keg 60L  HDPE barrel 5L, 10L, 20L, 30L, 200L  HDPE IBC 1000L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment. * For maintenance of dosing pumps, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles * For maintenance of circuit system, wear chemical goggles |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 3

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Comply with the instructions for use. * Apply only on non-porous surfaces. |

#### Risk mitigation measures

|  |
| --- |
| * For mixing and loading task, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles. |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.   Call 112/ambulance for medical assistance.   * Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid * IF SWALLOWED:   Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.   * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| * Shelf life: 1 year * Protect from frost. * Protect from direct sunlight. * Do not store above 30°C. |

### Other information

|  |
| --- |
| * Foaming products * The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. * The applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the OXENA FAMILY family. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 detergence pro Oxena  JAVEL DETERGENTE LE GLOBE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 detergence citron pro Oxena  JAVEL DETERGENTE CITRON LE GLOBE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 detergence eucalyptus pro Oxena  JAVEL DETERGENTE EUCALYPTUS LE GLOBE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 detergence pin pro Oxena | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 pro Oxena  EAU DE JAVEL LE GLOBE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 eucalyptus pro Oxena  EAU DE JAVEL EUCALYPTUS LE GLOBE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 citron pro Oxena  EAU DE JAVEL CITRON LE GLOBE  Eau de Javel nettoyante 2.6% parfumé citron Bernard | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

**Part II - Second information level - meta SPC 4**

### Meta SPC 4 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 4 – Bleach 2.6% non-professional |
| --- | --- |

#### Suffix to the authorisation number

| 4 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2, 4 |
| --- | --- |

### Meta SPC 4 composition

#### Qualitative and quantitative information on the composition of the meta SPC 4

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 | 27.1 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical concentrate is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the purity of NaOCl in TK concentrate is ranging from 96 to 145g/kg.

#### Type(s) of formulation of the meta SPC 4

|  |
| --- |
| SL – soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Irri. 2  Eye Dam. 1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H315: Causes skin irritation  H318: Causes serious eye damage  H400: Very toxic to aquatic life.  H411: Toxic to aquatic life with long-lasting effects. |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| Signal words | GHS05 Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H315: Causes skin irritation  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effect. |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand  P102: Keep out of reach of children  P103: Read label before use  P264: Wash … thoroughly after handling.  P273: Avoid released to the environment  P302+P352: IF ON SKIN: Wash with plenty of soap and water  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor/physician  P321: Specific treatment (see … on this label).  P332+P313: If skin irritation occurs: Get medical advice/attention.  P362+P364: Take off contaminated clothing and wash before reuse.  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
| Suppl. hazard statement |  |
|  | |
| Note | EUH 206: Warning! Do not use together with other products. May release dangerous gases (chlorine). |

### Authorised use(s) of the META SPC 4

#### Use description[[6]](#footnote-7)

Table 19. Use # 1 – Disinfection of sanitary installations

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Medical sector  Non medical sector |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | **Non medical sector:**  Clean conditions:  Bacteria (obligatory): 403 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 403 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 1075 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 1881 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1881 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2149 mg/L a.c, contact time: 15 min  **Medical sector:**  Clean conditions only:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 403 mg/L a.c,  Bacteria, yeasts and fungi (optional): 1075 mg/L a.c |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 20L  HDPE bottle 1L, 2L, 5L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

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|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 20. Use # 2 – Disinfection of hard surfaces (non medical sector)

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Non medical sector |
| **Application method(s)** | mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Bacteria (obligatory): 403 mg/L a.c, contact time: 5 min  Yeasts (optional): 269 mg/L a.c, contact time: 15 min  Fungi (optional): 1075 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 1881 mg/L a.c, contact time: 5 min  Yeasts (optional): 1075 mg/L a.c, contact time: 15 min  Fungi (optional): 2149 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 20L  HDPE bottle 1L, 2L, 5L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 5 or 15 minutes (depending on the target organism), then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food. * Do not touch the surface until it is rinsed and totally dried * Children should not be present during disinfection and until the surface is rinsed and dry * Animals should not be present during disinfection and until the surface is rinsed and dry |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 21. Use # 5 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | Mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Contact time: 15 min  Bacteria, yeasts (obligatory): 403 mg/L a.c  Bacteria, yeasts and fungi (optional): 1075 mg/L a.c  Dirty conditions:  Contact time: 15 min  Bacteria, yeasts (obligatory): 1881 mg/L a.c,  Bacteria, yeasts and fungi (optional): 2149 mg/L a.c |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | HDPE can 1L, 2L, 5L, 20L  HDPE bottle 1L, 2L, 5L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 15 minutes, then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment * Do not touch the surface until it is rinsed and totally dried * Children should not be present during disinfection and until the surface is rinsed and dry * Animals should not be present during disinfection and until the surface is rinsed and dry |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 4

#### Instructions for use

|  |
| --- |
| * The products should not be used in conjunction with acids or ammonia. * Comply with the instructions for use * Apply only on non-porous surfaces |

#### Risk mitigation measures

|  |
| --- |
| * Washing on hands after use * Avoid contact with eyes * A child proof closure is required |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.   Call 112/ambulance for medical assistance.   * Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid * IF SWALLOWED:   Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.   * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. * If medical advice is needed, have product container or label at hand. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| * Shelf life: 1 year * Protect from frost. * Protect from direct sunlight. * Do not store above 30°C. * Keep out of reach of children and non-target animals/pets. |

### Other information

|  |
| --- |
| * Foaming products * The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. * The packaging must be adapted with a child proof closure. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 GP Oxena  TOP BUDGET EAU JAVEL 5L  NETTO EAU DE JAVEL 5L  APTA JAVEL NATURE 2L  ECO+ - EAU DE JAVEL 5L  ECO+ - EAU DE JAVEL 2L  JAVEL 5L NON PARFUMEE TLJ  JAVEL 5L NON PARFUMEE LEADER PRICE  JAVEL 2L NON PARFUMEE TLJ  JAVEL 2,6% DISTRICONCEPT  JAVEL 5L SANS PARFUM TLJ  JAVEL 5L SANS PARFUM LEADER PRICE  JAVEL 2L SANS PARFUM TLJ  JAVEL 2,6% C.A. 5L SANS PARFUM TLJ  JAVEL 2,6% C.A. 5L SANS PARFUM LEADER PRICE  EAU DE JAVEL NON PARFUMEE ECO+ 5L  EAU DE JAVEL NON PARFUMEE ECO+ 2L | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 pin GP Oxena | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |
|  | | | | | |
| **Trade name(s)** | Javel 2.6 eucalyptus GP Oxena  APTA JAVEL EUCALYPTUS 2L  CLAIR - JAVEL PARFUMEE EUCALYPTUS 2L  JAVEL 2L PARFUMEE ECALYPTUS CASINO  JAVEL 2L PARFUMEE EUCALYPTUS LEADER PRICE  NETTO EAU JAVEL PARFUMEE 2L  JAVEL 2,6% C.A. 2L PARFUM ECALYPTUS CASINO  JAVEL 2,6% C.A. 2L PARFUM EUCALYPTUS LEADER PRICE  EAU DE JAVEL EUCALYPTUS MARQUE REPERE 2L | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 lavande GP Oxena  APTA JAVEL LAVANDE 2L  EAU DE JAVEL PARFUMEE FRAICHEUR LAVANDE U BIDONS 2 LITRES | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 2.6 citron GP Oxena  CLAIR - JAVEL PARFUMEE CITRON 2L  EAU DE JAVEL PARFUM CITRON U BIDON 2 LITRES  EAU DE JAVEL CITRON MARQUE REPERE 2L | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 2.6 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 27.1 |

**Part II - Second information level - meta SPC 6**

### Meta SPC 6 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 6 – Bleach 4.8% non-professional |
| --- | --- |

#### Suffix to the authorisation number

| 6 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2, 4 |
| --- | --- |

### Meta SPC 6 composition

#### Qualitative and quantitative information on the composition of the meta SPC 6

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.8 | 4.8 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 50.0 | 50.0 |

Note that no technical material TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical concentrate is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180g/kg. For this dossier, the purity of NaOCl in TK concentrate is ranging from 96 to 145g/kg.

#### Type(s) of formulation of the meta SPC 6

|  |
| --- |
| SL – soluble concentrate |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Skin Irri. 2  Eye Dam. 1  Aquatic acute 1  Aquatic chronic 2 |
| Hazard statement | H290: May be corrosive to metals  H315: Causes skin irritation  H318 : Causes serious eye damage  H400: Very toxic to aquatic life.  H411: Toxic to aquatic life with long-lasting effects. |
| Suppl. hazard statement |  |
|  | |
| **Labelling** | |
| Signal words | GHS05 Danger (Dgr) |
| Hazard statements | H290: May be corrosive to metals  H315: Causes skin irritation  H318: Causes serious eye damage  H410: Very toxic to aquatic life with long lasting effect. |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand  P102: Keep out of reach of children  P103: Read label before use  P264: Wash … thoroughly after handling.  P273: Avoid released to the environment  P302+P352: IF ON SKIN: Wash with plenty of soap and water.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER or doctor/physician  P321: Specific treatment (see … on this label).  P332+P313: If skin irritation occurs: Get medical advice/attention.  P362+P364: Take off contaminated clothing and wash before reuse.  P391: Collect spillage  P501: Dispose of contents/container in accordance with the national regulation |
| Suppl. hazard statement |  |
|  | |
| Note | EUH031: Contact with acids liberates toxic gas.  EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). |

### Authorised use(s) of the META SPC 6

#### Use description[[7]](#footnote-8)

Table 22. Use # 1 – Disinfection of sanitary installations

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Medical sector  Non medical sector |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | **Non medical sector:**  Clean conditions:  Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 1075 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1961 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min  **Medical sector:**  Clean conditions only:  Contact time: 15 min  Bacteria / Yeasts (obligatory): 413 mg/L a.c,  Bacteria, yeasts and fungi (optional): 1135 mg/L a.c |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | PVC berlingot 250 mL  HDPE bottle 1 L  HDPE can 5 L, 20L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of microorganisms to the patient. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food. |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 23. Use # 2 – Disinfection of hard surfaces (non medical sector)

|  |  |
| --- | --- |
| **Product Type** | **PT 2** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor  Non medical sector |
| **Application method(s)** | Mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min  Dirty conditions:  Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min  Bacteria and yeasts (optional): 1961 mg/L a.c, contact time: 15 min  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | PVC berlingot 250 mLHDPE bottle 1 L  HDPE can 5 L, 20L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 5 or 15 minutes (depending on the target organism), then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Avoid any direct or indirect contact with food * Do not touch the surface until it is rinsed and totally dried * Children should not be present during disinfection and until the surface is rinsed and dry * Animals should not be present during disinfection and until the surface is rinsed and dry |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

#### Use description

Table 24. Use # 5 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | **PT 4** |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor |
| **Application method(s)** | mopping, pouring, wiping, scrubbing (no mechanical action) |
| **Application rate(s) and frequency** | Clean conditions:  Contact time: 15 min  Bacteria, yeasts (obligatory): 413 mg/L a.c  Bacteria, yeasts and fungi (optional): 1135 mg/L a.c  Dirty conditions:  Contact time: 15 min  Bacteria, yeasts (obligatory): 1961 mg/L a.c,  Bacteria, yeasts and fungi (optional): 2270 mg/L a.c |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | PVC berlingot 250 mLHDPE bottle 1 L  HDPE can 5 L, 20L |

#### Use-specific instructions for use

|  |
| --- |
| * Clean carefully the surfaces before application of the product for application in clean conditions. * Apply without mechanical action on the surfaces intended to be treated and cover the entire surface. * Allow to take effect for at least 15 minutes, then mop/wipe/scrub if required. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Rinse surfaces after treatment. * Do not touch the surface until it is rinsed and totally dried * Children should not be present during disinfection and until the surface is rinsed and dry * Animals should not be present during disinfection and until the surface is rinsed and dry |

#### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
|  |

#### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
|  |

#### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
|  |

### General directions for use of the meta SPC 6

#### Instructions for use

|  |
| --- |
| * Products should not be used in conjunction with acids or ammonia. * Comply with the instructions for use * Apply only on non-porous surfaces |

#### Risk mitigation measures

|  |
| --- |
| * Washing on hands after use * Avoid contact with eyes * A child proof closure is required |

#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| * IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. * IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes.   Call 112/ambulance for medical assistance.   * Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid * IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. * If medical advice is needed, have product container or label at hand |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

#### Conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| * Shelf life: 12 months * Protect from frost. * Protect from direct sunlight. * Do not store above 30°C. * Keep out of reach of children and non-target animal/pets |

### Other information

|  |
| --- |
| * The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee the efficacy of the product during its application. * The packaging must be adapted with a child proof closure. |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | Javel 4.8 GP Oxena  APTA JAVEL DOSE 3X250ML  NETTO JAVEL DOSE 3X250ML  ECO+ - EAU DE JAVEL 3X250 ML  BERLINGOTS JAVEL CONCENTREE 3x250ML SANS PARFUM TLJ  BERLINGOT JAVEL CONCENTREE SANS PARFUM 3x250ML LEADER PRICE  MIC  JAVEL 4,8% OXENA  JAVEL 4,8% DISTRICONCEPT  BERLINGOTS JAVEL CONCENTREE 3x250ML NON PARFUMEE TLJ  BERLINGOTS JAVEL CONCENTREE NON PARFUMEE 3x250ML LEADER PRICE  BERLINGOTS JAVEL 4,8% C.A. 3x250ML NON PARFUMEE TLJ  BERLINGOTS JAVEL 4,8% C.A. NON PARFUMEE 3x250ML LEADER PRICE  EAU DE JAVEL NON PARFUMEE ECO+ 3X250ML | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2) | / | Active substance | / | / | 4.8 |
| Sodium hypochlorite (technical solution with minimum purity of  9.6% w/w as av. Cl) | Sodium hypochlorite | Non active substance | 7681-52-9 | 231-668-3 | 50.0 |
|  |  |  |  |  |  |

### Packaging of the biocidal product

| **Meta-SPC** | **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| --- | --- | --- | --- | --- | --- | --- |
| Meta-SPC1: Industrial uses and professional uses | Can | 5L, 10L, 20L, 25L, 30L | HDPE | Hermetically closed.  Screw cap. Venting cap | Professional | Yes |
| Barrel | 5L, 10L, 20L, 30L, 60L, 200L | HDPE |
| Drum | 5L, 20L | HDPE | Auto-seal with ring inviolability. Venting cap.  Hermetically closed |
| Bottle | 5L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Keg | 60L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| IBC | 1000L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Meta-SPC 2 – Bleach 9.6 - 12.5% - Professional | Bottle | 250 mL | HDPE | Hermetically closed.  Screw cap. Venting cap. | Professional | Yes |
| Can | 250 mL, 5L, 10L, 20L, 30L, 200 L, 1000 L |
| Barrels | 5L, 10L, 20L, 30L, 60L |
| Drum | 2L, 5L, 10L, 20L | HDPE | Auto-seal with ring inviolability. Venting cap. Screw cap.  Hermetically closed |
| 30L | HDPE | Polypropylene (PP)  Venting cap.  Screw cap.  Hermetically closed |
| Meta-SPC 3 – Bleach 2.6% professional | Barrels | 5L, 10L, 20L, 30L | HDPE | Hermetically closed.  Screw cap. | Professional | Yes |
| Can | 1L, 2L, 5L, 10L, 20L, 25L, 30L | HDPE | Hermetically closed.  Screw cap. |
| Drum | 1L, 2L, 5L, 10L, 20L | HDPE | Auto-seal with ring inviolability. Venting cap.  Screw cap.  Hermetically closed |
| 30L | HDPE | Polypropylene (PP)  Venting cap.  Screw cap.  Hermetically closed |
| Bottle | 1L, 2L, 5L | HDPE | Screw cap.  Hermetically closed. |
| Keg | 60L | HDPE | Screw cap.  Hermetically closed. |
| Barrel | 200L | HDPE | Screw cap. Hermetically closed. |
| IBC | 1000L | HDPE | Screw cap. Hermetically closed. |
| Meta-SPC 4 – Bleach 2.6% non-professional | Can | 1L, 2L, 5L, 20L | HDPE | Screw cap. Hermetically closed. | Non-professional | Yes |
| Bottle | 1L, 2L, 5L | HDPE | Hermetically closed.  Screw cap. |
| Meta-SPC 5 – Anti-lichen - Professional | Can | 5L, 20L | HDPE | Hermetically closed.  Screw cap. Venting cap | Professional | Yes |
| Can | 1L, 5L, 20L, 25L, 30L, 60L | HDPE | Hermetically closed  (Tamperproof cap with event) |
| Barrel | 200L |
| Barrel | 200L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Drum | 220L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| 5L, 10L, 30L | HDPE | Polypropylene (PP)  Venting cap.  Hermetically closed.  Screw cap. |
| IBC | 1000L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Bottle | 1L, 2L, 5L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Keg | 60L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Meta-SPC 6 – Bleach 4.8% non-professional | In dose (berlingot) | 250 mL | PVC | Hermetically closed.  Screw cap. Hermetically closed | Non-professional | Yes |
| Bottle | 1L | HDPE |
| Can | 5L, 20 L | HDPE | Hermetically closed.  Screw cap. Venting cap |
| Meta-SPC 7 – Thick Bleach professional | Bottle | 1L | HDPE | Polypropylene (PP)  self-jointant  FLIP TOP CAPS  Hermetically closed | Professional | Yes |
| Can | 5L | HDPE | Hermetically closed.  Screw cap. Venting cap | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

A list of studies performed on products is provided in the PAR in Annex 3. No new study is provided related to active substance.

Physico-chemical properties: Studies were performed on several products from the Family.

Efficacy data: Studies were performed on several products from the Family.

Toxicology data: Studies were performed on several products from the Family

Residues data: No specific residue data were submitted in the context of this dossier.

Ecotoxicological data: No ecotoxicology studies were submitted in the context of this dossier.

#### Access to documentation

A letter of access to the data of the CAR of sodium hypochlorite (PT2) has been submitted by Euro Chlor (owners of studies on sodium hypochlite for PTs 1-5) and allows Laboratoire Oxena to refer to active substance data.

## Assessment of the biocidal product family

### Intended use(s) as applied for by the applicant

The uses below are the ones applied for by the applicant.

Application rates are expressed as active chlorine as indicated in assessment report but also as mL of product to help the consumer to perform its dilutions. The following formula is used for conversion:

Ci: initial concentration (g/L)

Vi : initial volume (L)

Cf : final concentration desired (g/L) → minimum efficacy dose

Vf: final volume on 1 liter (L)

Table 1. Intended use # 1 – Disinfection of sanitary installations

|  |  |
| --- | --- |
| **Product Type** | TP 2 |
| **Meta-SPCs** | 2, 3, 4, 6, 7 |
| **Where relevant, an exact description of the authorised use** | Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.).  No mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Non medical sector  Medical sector  Indoor |
| **Application method(s)** | Pouring |
| **Application rates and frequency – Meta SPC 2 – Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Application rates and frequency – Meta SPC 3 - Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 2000 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **177** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **77** | | Virus | Dirty | 15 min | **80** | |
| **Application rates and frequency – Meta SPC 4 - Bleach 2.6% non-professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 1820 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **70** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **80** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **40** | | Virus | Dirty | 15 min | **80** | |
| **Application rate(s) and frequency – Meta SPC 6 - Bleach 4.8% non-professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 1820 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 4.8%/L)** | | Bacteria | Clean | 5 min | **8** | | Bacteria | Dirty | 5 min | **38** | | Fungal spore | Clean | 15 min | **22** | | Fungal spore | Dirty | 15 min | **44** | | Yeast | Clean | 15 min | **5** | | Yeast | Dirty | 15 min | **22** | | Virus | Dirty | 15 min | **44** | |
| **Application rate(s) and frequency – Meta SPC 7 - Thick Bleach professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Dirty | 5 min | 1610 mg/L | | Fungal spore | Dirty | 15 min | 1610 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Gel javel)** | | Bacteria | Dirty | 5 min | **70** | | Fungal spore | Dirty | 15 min | **70** | |
| **Category(ies) of users** | Professional and non-professional |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 2. Intended use # 2 – Disinfection of hard surfaces

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Meta-SPCs** | 2, 3, 4, 6, 7 |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing.  With mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Non medical sector  Medical sector  Indoor |
| **Application method(s)** | Spraying, wiping, pouring mopping or scrubbing |
| **Application rate(s) and frequency – Meta SPC 2 – Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Application rate(s) and frequency – Meta SPC 3 - Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **80** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **40** | | Virus | Dirty | 15 min | **80** | |
| **Application rate(s) and frequency – Meta SPC 4 - Bleach 2.6% non-professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 1820 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **70** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **80** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **40** | | Virus | Dirty | 15 min | **80** | |
| **Application rate(s) and frequency – Meta SPC 6 - Bleach 4.8% non-professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 1820 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 4.8%/L)** | | Bacteria | Clean | 5 min | **8** | | Bacteria | Dirty | 5 min | **38** | | Fungal spore | Clean | 15 min | **22** | | Fungal spore | Dirty | 15 min | **44** | | Yeast | Clean | 15 min | **5** | | Yeast | Dirty | 15 min | **22** | | Virus | Dirty | 15 min | **44** | |
| **Application rate(s) and frequency – Meta SPC 7 - Thick Bleach professional** | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Dirty | 5 min | 1610 mg/L | | Fungal spore | Dirty | 15 min | 1610 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Gel javel)** | | Bacteria | Dirty | 5 min | **70** | | Fungal spore | Dirty | 15 min | **70** | | |
| **Category(ies) of users** | Professional and non-professional |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 3. Intended use # 3 – Disinfection of hard surfaces (medical sector)

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Meta-SPCs** | 2, 3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing.  With mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Medical sector  Indoor |
| **Application method(s)** | Spraying, wiping, pouring, mopping or scrubbing |
| **Application rate(s) and frequency – Meta SPC 2 – Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 5 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 5 min | 2000 mg/L | | Virus | Dirty | 5 min | 3120 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **22** | | Fungal spore | Clean | 15 min | **11** | | Fungal spore | Dirty | 5 min | **48** | | Yeast | Clean | 15 min | **3** | | Yeast | Dirty | 5 min | **21** | | Virus | Dirty | 5 min | **32.5** | |
| **Application rate(s) and frequency – Meta SPC 3 - Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 5 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 5 min | 2000 mg/L | | Virus | Dirty | 5 min | 3120 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 5 min | **177** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 5 min | **77** | | Virus | Dirty | 5 min | **120** | |
| **Category(ies) of users** | Professional and non-professional |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 4. Intended use # 4 – Anti-lichen and anti-algae treatment of hard surfaces

|  |  |
| --- | --- |
| **Product Type** | PT 2 |
| **Meta-SPCs** | 5 |
| **Where relevant, an exact description of the authorised use** | Anti-lichen and anti-algae treatment of hard surfaces such as wall, floor, roof, etc.  No mechanical action |
| **Target organism (including development stage)** | **Algae & Lichens** |
| **Field of use** | Non medical sector  Outdoor |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | Max 1 treatment per year at 0.1L/m2 |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 5. Intended use # 5 – Disinfection of hard surfaces in contact with food

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Meta-SPCs** | 1, 2, 3, 4, 6, 7 |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces in contact with food (e.g. floors, walls, furniture, equipment, drains, sinks…).  With mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Food and feed area  Non medical sector  Indoor |
| **Application method(s)** | Spraying, wiping, mopping, scrubbing or pouring |
| **Application rate(s) and frequency – Meta SPC 1 - Food industry** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 275 mg/L | | Bacteria | Dirty | 5 min | 3300 mg/L | | Fungal spore | Clean | 15 min | 1650 mg/L | | Fungal spore | Dirty | 15 min | 2750 mg/L | | Yeast | Clean | 15 min | 400 mg/L | | Yeast | Dirty | 15 min | 1200 mg/L |   Viruses are not claimed in Meta-SPC1.   |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 5%/L)** | | Bacteria | Clean | 5 min | **5.5** | | Bacteria | Dirty | 5 min | **66** | | Fungal spore | Clean | 15 min | **33** | | Fungal spore | Dirty | 15 min | **55** | | Yeast | Clean | 15 min | **8** | | Yeast | Dirty | 15 min | **24** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 6.3%/L)** | | Bacteria | Clean | 5 min | **4.5** | | Bacteria | Dirty | 5 min | **52** | | Fungal spore | Clean | 15 min | **44** | | Fungal spore | Dirty | 15 min | **30** | | Yeast | Clean | 15 min | **6** | | Yeast | Dirty | 15 min | **19** | |
| **Application rate(s) and frequency – Meta SPC 2 - Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Application rate(s) and frequency – Meta SPC 3 - Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 2000 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **177** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **77** | | Virus | Dirty | 15 min | **80** | |
| **Application rates and frequency – Meta SPC 4 - Bleach 2.6% non-professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 1820 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **70** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **80** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **40** | | Virus | Dirty | 15 min | **80** | |
| **Application rates and frequency – Meta SPC 6 - Bleach 4.8% non-professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 1820 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 2080 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 1040 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 4.8%/L)** | | Bacteria | Clean | 5 min | **8** | | Bacteria | Dirty | 5 min | **38** | | Fungal spore | Clean | 15 min | **22** | | Fungal spore | Dirty | 15 min | **44** | | Yeast | Clean | 15 min | **5** | | Yeast | Dirty | 15 min | **22** | | Virus | Dirty | 15 min | **44** | |
| **Application rates and frequency – Meta SPC 7 - Thick Bleach professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Dirty | 5 min | 1610 mg/L | | Fungal spore | Dirty | 15 min | 1610 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Gel javel)** | | Bacteria | Dirty | 5 min | **70** | | Fungal spore | Dirty | 15 min | **70** | |
| **Category(ies) of users** | Professional and non-professional |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 6. Intended use # 6 – Disinfection of equipment/materials by spraying.

|  |  |
| --- | --- |
| **Product Type** | PT 2-4 |
| **Meta-SPCs** | 1, 2, 3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment/materials by spraying.  No mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Food and feed area  Indoor |
| **Application method(s)** | Spraying |
| **Application rates and frequency – Meta SPC 1 - Food industry** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 275 mg/L | | Bacteria | Dirty | 5 min | 3300 mg/L | | Fungal spore | Clean | 15 min | 1650 mg/L | | Fungal spore | Dirty | 15 min | 2750 mg/L | | Yeast | Clean | 15 min | 400 mg/L | | Yeast | Dirty | 15 min | 1200 mg/L |   **Viruses are not claimed in Meta-SPC1.**   |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 6.3%/L)** | | Bacteria | Clean | 5 min | **5.5** | | Bacteria | Dirty | 5 min | **66** | | Fungal spore | Clean | 15 min | **33** | | Fungal spore | Dirty | 15 min | **55** | | Yeast | Clean | 15 min | **8** | | Yeast | Dirty | 15 min | **24** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 5%/L)** | | Bacteria | Clean | 5 min | **4.5** | | Bacteria | Dirty | 5 min | **52** | | Fungal spore | Clean | 15 min | **44** | | Fungal spore | Dirty | 15 min | **30** | | Yeast | Clean | 15 min | **6** | | Yeast | Dirty | 15 min | **19** | |
| **Application rates and frequency – Meta SPC 2 - Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Application rates and frequency – Meta SPC 3 - Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 2000 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **177** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **77** | | Virus | Dirty | 15 min | **80** | |
| **Category(ies) of users** | Professional  Industrial (only for meta SPC 1) |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 7. Intended use # 7 – Disinfection of equipment/materials by immersion/soaking

|  |  |
| --- | --- |
| **Product Type** | PT 2- 4 |
| **Meta-SPCs** | 2, 3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment/materials by immersion/soaking.  No mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Food and feed area  Non medical sector  Indoor |
| **Application method(s)** | Immersion/soaking |
| **Application rates and frequency - Meta-SPC 2 – Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Application rates and frequency - Meta-SPC 3 – Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 2000 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **177** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **77** | | Virus | Dirty | 15 min | **80** | |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 7. Intended use # 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP)

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Meta-SPCs** | 1, 2, 3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  No mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Food and feed area |
| **Application method(s)** | Pouring |
| **Application rates and frequency – Meta SPC 1 - Food industry** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 275 mg/L | | Bacteria | Dirty | 5 min | 3300 mg/L | | Fungal spore | Clean | 15 min | 1650 mg/L | | Fungal spore | Dirty | 15 min | 2750 mg/L | | Yeast | Clean | 15 min | 400 mg/L | | Yeast | Dirty | 15 min | 1200 mg/L |   Viruses are not claimed in meta-SPC 1.   |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 5%/L)** | | Bacteria | Clean | 5 min | **5.5** | | Bacteria | Dirty | 5 min | **66** | | Fungal spore | Clean | 15 min | **33** | | Fungal spore | Dirty | 15 min | **55** | | Yeast | Clean | 15 min | **8** | | Yeast | Dirty | 15 min | **24** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 6.3%/L)** | | Bacteria | Clean | 5 min | **4.5** | | Bacteria | Dirty | 5 min | **52** | | Fungal spore | Clean | 15 min | **44** | | Fungal spore | Dirty | 15 min | **30** | | Yeast | Clean | 15 min | **6** | | Yeast | Dirty | 15 min | **19** | |
| **Application rates and frequency – Meta SPC 2 - Meta-SPC 2 – Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Application rates and frequency – Meta-SPC 3 – Bleach 2.6% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 390 mg/L | | Bacteria | Dirty | 5 min | 2080 mg/L | | Fungal spore | Clean | 15 min | 1040 mg/L | | Fungal spore | Dirty | 15 min | 4600 mg/L | | Yeast | Clean | 15 min | 260 mg/L | | Yeast | Dirty | 15 min | 2000 mg/L | | Virus | Dirty | 15 min | 2080 mg/L | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 2.6%/L)** | | Bacteria | Clean | 5 min | **15** | | Bacteria | Dirty | 5 min | **80** | | Fungal spore | Clean | 15 min | **40** | | Fungal spore | Dirty | 15 min | **177** | | Yeast | Clean | 15 min | **10** | | Yeast | Dirty | 15 min | **77** | | Virus | Dirty | 15 min | **80** | |
| **Category(ies) of users** | Professional  Industrial (only for meta SPC 1) |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

Table 9. Intended use # 9– Disinfection of inner surfaces in veterinary water systems

|  |  |
| --- | --- |
| **Product Type** | PT 4 |
| **Meta-SPCs** | 1, 2 |
| **Where relevant, an exact description of the authorised use** | Disinfection of inner surfaces in veterinary water systems.  No mechanical action |
| **Target organism (including development stage)** | **Bacteria**  *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus*  **Fungi**  *Aspergillus brasiliensis*  **Yeast**  *Candida albicans*  **Virus**  *Adenovirus*  *Murine norovirus* |
| **Field of use** | Food and feed area  Indoor |
| **Application method(s)** | Pouring |
| **Application rates and frequency – Meta SPC 1 - Food industry** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 275 mg/L | | Bacteria | Dirty | 5 min | 3300 mg/L | | Fungal spore | Clean | 15 min | 1650 mg/L | | Fungal spore | Dirty | 15 min | 2750 mg/L | | Yeast | Clean | 15 min | 400 mg/L | | Yeast | Dirty | 15 min | 1200 mg/L |   **Viruses are not claimed in Meta-SPC1.**   |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 5%/L)** | | Bacteria | Clean | 5 min | **5.5** | | Bacteria | Dirty | 5 min | **66** | | Fungal spore | Clean | 15 min | **33** | | Fungal spore | Dirty | 15 min | **55** | | Yeast | Clean | 15 min | **8** | | Yeast | Dirty | 15 min | **24** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as mL Bleach 6.3%/L)** | | Bacteria | Clean | 5 min | **4.5** | | Bacteria | Dirty | 5 min | **52** | | Fungal spore | Clean | 15 min | **44** | | Fungal spore | Dirty | 15 min | **30** | | Yeast | Clean | 15 min | **6** | | Yeast | Dirty | 15 min | **19** | |
| **Application rates and frequency – Meta SPC 2 – Bleach 9.6 - 12.5% professional** | |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(as active chlorine)** | | Bacteria | Clean | 5 min | 470 mg/L | | Bacteria | Dirty | 5 min | 2490 mg/L | | Fungal spore | Clean | 15 min | 1245 mg/L | | Fungal spore | Dirty | 15 min | 3320 mg/L | | Yeast | Clean | 15 min | 830 mg/L | | Yeast | Dirty | 15 min | 1245 mg/L | | Virus | Dirty | 15 min | 2080 mg/L |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach 9.6%/L)** | | Bacteria | Clean | 5 min | **5** | | Bacteria | Dirty | 5 min | **26** | | Fungal spore | Clean | 15 min | **13** | | Fungal spore | Dirty | 15 min | **35** | | Yeast | Clean | 15 min | **9** | | Yeast | Dirty | 15 min | **13** | | Virus | Dirty | 15 min | **22** |  |  |  |  |  | | --- | --- | --- | --- | | **Micro-organism** | **Soiling conditions**  **Clean/Dirty** | **Contact time** | **Application rate recommended**  **(mL of Bleach12.5%/L)** | | Bacteria | Clean | 5 min | **4** | | Bacteria | Dirty | 5 min | **20** | | Fungal spore | Clean | 15 min | **10** | | Fungal spore | Dirty | 15 min | **26** | | Yeast | Clean | 15 min | **7** | | Yeast | Dirty | 15 min | **10** | | Virus | Dirty | 15 min | **17** | |
| **Category(ies) of users** | Professional  Industial (only for meta SPC 1) |
| **Pack sizes and packaging material** | Please refer to section 2.1.7 Packaging of the biocidal product. |

### Physical, chemical and technical properties

New studies were provided for this family. The products are aqueous formulation of sodium chloride (SL formulation). Products of meta SPC 5 and 7 are ready to use. Other products should be diluted prior using.

The packaging material claimed for this family is made of HDPE (can, barrel, drum, bottle, keg and IBC and PVC berlingot. Berlingots are only claimed for meta SPC 6.

The biocidal product is a Soluble Concentrate formulation.

The products do not contain hydrocarbons or H304 co-formulant content ≥10%.

**Applicant justification on the choice of the products to be tested in each meta SPC:**

*“Storage stability studies (accelerated storage and long term storage at ambient temperature) were performed on 9 formulations. Those formulations were selected in order to evaluate the effect of parameters such as active substance concentration, perfume, coformulants related to detergent function and atypical composition on the stability of the products. To that end, storage stability studies were performed on the following products:*

* *OXE ALCA (meta SPC 1)*
* *OXE ALCA CHLORE MOUSSANT (meta SPC 1)*
* *JAVEL 12,5 PRO OXENA (meta SPC 2)*
* *JAVEL 2,6 PRO/GP OXENA (meta SPC 3)*
* *JAVEL 2,6 CITRON PRO/GP OXENA (meta SPC 3)*
* *JAVEL 2,6 DETERGENCE CITRON PRO OXENA (meta SPC 3)*
* *JAVEL 6 EUCALYPTUS (meta SPC 5)*
* *JAVEL 4,8 GP OXENA (meta SPC 6)*
* *GEL JAVEL PRO OXENA (meta SPC 7)*

*To evaluate the impact of sodium hypochlorite concentration on the stability of formulations, the products Javel 12.5, Javel 4.8, Javel 2.6 have been selected. These products cover respectively high, medium and low sodium hypochlorite concentrations and have similar composition (the only difference is the active substance content). According the EU Risk assessment report of Sodium hypochlorite, the degradation of sodium hypochlorite is dependant on the concentration, the more stable solutions are those of low sodium hypochlorite concentration. As the only difference between Javel 9.6 and Javel 12.5 is the active substance content, and as Javel 12.5 could be considered as a worst-case due to its higher chlorine content, the shelf life of Javel 12.5 will be extrapolated to Javel 9.6. Javel 4.8 was selected also due to its specific packaging, which is a PVC berlingot while for other formulations HDPE containers are used.*

*To evaluate the impact of the perfume on the stability of formulations, the product Javel 2.6 citron have been selected. As fragrance Javel 2.6 formulations (i.e. Javel 2.6 citron, Javel 2.6 eucalyptus, Javel 2.6 lavande and Javel 2.6 pin) have very similar composition (the only difference is the perfume, other coformulant are identical and present at same amount), the shelf-life of Javel 2.6 citron will be extrapolated to Javel 2.6 eucalyptus, Javel 2.6 lavande and Javel 2.6 pin.*

*To evaluate the impact of the co-formulants related to detergent function, the product Javel 2.6 détergence citron have been selected. As Javel 2.6 détergence formulations (i.e. Javel 2.6 détergence, Javel 2.6 détergence citron and Javel 2.6 détergence eucalyptus) have very similar composition (the only difference is the perfume, other coformulant are identical and present at same amount), the shelf-life of Javel 2.6 détergence citron will be extrapolated to Javel 2.6 détergence, Javel 2.6 détergence pin and Javel 2.6 détergence eucalyptus.*

*The products OXE ALCA, OXE ALCA CHLORE MOUSSANT and GEL JAVEL PRO OXENA have specific compositions, so stability studies were performed on each products.*

*Viscosity, surface tension and relative density are physical properties not included in storage stability studies but are required for a soluble concentrate formulation. These properties were determined on 6 products. The compositions of those products are considered as worst-cases with regard to the active substance and co-formulant contents and the assessment of their physical, chemical and technical properties covers all the products included in the biocide product family.**Physical, chemical and technical properties were determined for the following products:*

* *OXE ALCA*
* *OXE ALCA CHLORE MOUSSANT*
* *JAVEL 12,5 PRO OXENA*
* *JAVEL 2,6 CITRON PRO OXENA*
* *JAVEL 2,6 DETERGENCE CITRON PRO OXENA*
* *GEL JAVEL PRO OXENA*

*For the determination of viscosity, surface tension and relative density, Javel 12.5 has been selected regarding its high sodium hypochlorite concentration, Javel 2.6 citron has been selected to evaluate the impact the perfume, Javel 2.6 détergence citron to evaluate the impact of coformulant related to detergent function, OXE ALCA, OXE ALCA CHLORE MOUSSANT and GEL JAVEL PRO OXENA have been selected due to their atypical composition (various coformulants at various concentrations).*

*Please see the document BPF overview in Section 13 of IUCLID for full product compositions.”*

eCA agrees with the choices proposed. Regarding the influence of perfumes, please refer to confidential annex for read across.

**Note**

Some products have several names. The table below summarizes the names exisiting for a same formulation:

|  |  |
| --- | --- |
| **Reference name** | **Alternative name** |
| Javel 4.8 | Javel MIC |
| Clorigel | Gel Javel  Gel Javel Pro  Gel Javel Pro Oxéna  Chlorigel |
| Extimum | Anti lichen  Javel 6 |
| Oxe Alca | Alca |
| Oxe Alca Chlore Moussant | Decap ACM |
| Javel 2.6 détergence citron | Javel 2.6 détergente citron |
| Javel 2.6 citron | Javel Fraicheur citron  Javel 2.6 parfum citron |

It should also be noticed that a formulation can be present in two different meta SPC (one SPC for professional and another for non professional). Consequently, formulations with the name GP (“Grand Public” meaning non professional users) or PRO (for professional users) are identical. This is the case for products of meta SPC 3 and 4.

Mentions EUH 206 and 031 are sometimes proposed by eCA:

* EUH206 is only applicable for non professional users and when active chlorine content in biocidal products is > 1% w/w.
* EU031 is applicable when sodium hypochlorite content in biocidal products is ≥ 5% w/w.

**Meta SPC 1 – FOOD INDUSTRY**

**OXE ALCA**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **GLP** | **Reference** | **eCA assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | Transparent yellow liquid. | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | Bitter smell. | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | pH of 1% dilution at 19.3°C : 12.2 | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | Acceptable. Neat pH is not available but it is expected to be >11.5 as diluted pH is 12.2. |
| Acidity / alkalinity | CIPAC MT 191 | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | Alkalinity: 9.5% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | Acceptable. |
| Relative density / bulk density | OECD 109 (pycnometer method) | **OXE ALCA**  6.3% of active chlorine  18D001871 | Density: 1.1341 g/mL (mean of two determinations) | Y | Peysson, W. (2019)  Report RRCo-000352\_01 | Acceptable. |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  CIPAC MT  46.3  75.3  191  47.2  179 | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 6.67% w/v | 2.21% w/v  (-66.9%) | | **Sodium chlorate content** | 0.30% w/v  (corresponding to 4.5% of the active chlorine content) | 2.41% w/v | | **Ratio sodium chlorate/av chlorine (%w/w)** | 4.5% | 109% | | **Appearance** | Transparent yellow liquid with bitter smell. After storage, the bottom of the flask is cloudy. | | | **pH 1% at 20°C** | 12.2 at 19.3°C | 12.2 at 19.3°C | | **Alcalinity/Acidity** | 9.5 | 6.9 | | **Dilution stability**  (at 3% w/v) | No residues (the bottom of the flask is cloudy) | No residues (the bottom of the flask is cloudy) | | **Persistent foam**  (at 3% w/v) | 0 mL after 1 min | 0 mL after 1 min |   Applicant:  Significant decrease of the active substance content (-67%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103 (chlorate)  CIPAC MT  75.3  191  47.2  41 | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | The sample was stored at ambient temperature (20°C) in 5L HDPE bottle   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 3 months**  **opaque HDPE** | **After 4 months**  **opaque HDPE** | **After 5 months**  **opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 6.67% w/v | 5.73% w/v  (-14.1%) | 5.47% w/v  (-18.0%) | 5.50% w/v  (-17.5%) | | **Sodium chlorate content** | 0.3% w/v | 0.72% w/v | 0.82% w/v | 0.89% w/v | | **Ratio sodium chlorate/active chlorine (limit 5.4% w/w according to the regulation)** | 4.5% | 12.6% | 15% | 16% | | **Appearance** | Product: Transparent yellow liquid with bitter smell.  Packaging: No crack, no swelling, no change of color. | | | | | **pH 1% at 20°C** | 12.2 | Not determined | 12.1 | Not determined | | **Alcalinity/Acidity** | 9.50 | Not determined | 7.35 | Not determined | | **Dilution stability**  (at 3% w/v) | No residues (the bottom of the flask is cloudy) | Not determined | No residues (the bottom of the flask is cloudy) | Not determined | | **Persistent foam**  (at 3% w/v) | 0 mL after 1min | Not determined | 0 mL after 1 min | Not determined |   Applicant: Significant decrease of the active substance content (-18%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 5-month storage at ambient temperature. There is no significant change in the other technical properties.  Therefore, to set a shelf life, data on efficacy and degradation products must be available.  Efficacy is demonstrated after 5-month storage (equivalent to a degradation of 18% of AS). See section 2.2.5.5. The sodium chlorate content after 5-month storage is taken into account for the risk assessment for human and environment.  Provided those explanations are considered appropriate, a shelf life of 5 months could be provided. | N (mid term report) | Peysson, W. (2020)  Report RRCo-000380\_01 | The content of active chlorine decreases by more than 10%.  The ratio sodium chlorate/av chlorine exceeds the limit of 5.4% after 3, 4 and 5 months. Refer to human health section regarding conclusion on chlorate content. According to efficacy section, the product remains efficacious after 6 months. A shelf life of 5 months is acceptable.  Other properties and compatibility with HDPE are acceptable. The pH remains also higher than 11 after storage, which is important to stabilize the active ingredient. |
| Storage stability test – **low temperature stability test for liquids** |  |  | Applicant: Not needed, mention is made on the label not to store under 0°C. |  |  | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Applicant: the active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. |  |  | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | See ”Storage stability test – **long term storage at ambient temperature”** |  |  | According to the results of accelerated storage stability study, the product should be kept below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See ”Storage stability test – **long term storage at ambient temperature”** |  |  | See results of long term storage stability study performed with HDPE bottle. |
| Wettability |  |  | Not relevant (liquid formulation) |  |  | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant (liquid formulation) |  |  | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test |  |  | Not relevant (liquid formulation) |  |  | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not relevant |  |  | Not relevant for SL formulation. |
| Disintegration time |  |  | Not relevant (liquid formulation) |  |  | Not relevant for SL formulation. |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not relevant (liquid formulation) |  |  | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | No foam observed after 10 seconds at the concentration of 3% w/v.  The level of foam does not exceed 60mL after 1 min. | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | Acceptable. The product is not a foaming formulation. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Degree of dissolution and dilution stability | CIPAC MT 41 | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | At 3% m/v concentration, after 18h, no residues is observed but the bottom of the flask is cloudy.  Applicant: Nevertheless, no blockage of the application equipment or unacceptable risk is expected since the formulation is not intended to be applied by spraying. | Y | Peysson, W. (2019)  Report RRCo-000324\_01 | Acceptable.  Note that according to the uses claimed for meta SPC 1, spraying is an application method. |
| Surface tension | OECD 115 EU A.5 (ring method) | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | Pure: 46.0 mN/m at 19.9°C  The test item was considered as surface-active. | Y | Demangel, B. (2019), Report No. 18-918046-001 | Acceptable. The product is surface active. |
| Viscosity | OECD 114 (viscometer with rotational spindles) | **OXE ALCA**  6.3% of active chlorine  Batch 18G002020 | The mean dynamic viscosity of the test item was:   * At 20°C: ranging from 2.64 mPa.s (30 RPM) to 2.76 mPa.s (150RMP) * At 40°C: ranging from 1.66mPa.s (40 RPM) to 1.68 mPa.s (110RPM) | Y | Demangel, B. (2019), Report No. 18-918046-001 | Acceptable. The product is a newtonian fluid. |

**OXE ALCA CHLORE MOUSSANT**

The biocidal product is a Soluble Concentrateformulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | Transparent yellow slightly viscous liquid. | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | Bitter smell. | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | pH of 1% dilution at 19.3°C : 12.2 | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | Acceptable. Neat pH is not available but it is expected to be >11.5 as diluted pH is 12.2. |
| Acidity / alkalinity | CIPAC MT 191 | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | Alkalinity: 8.4% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | Acceptable |
| Relative density / bulk density | OECD 109 (pycnometer method) | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 126200918001 | Density: 1.1451 g/mL (mean of two determinations) | Y | Peysson, W. (2019)  Report RRCo-000353\_01 | Acceptable |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)  CIPAC MT  46.3  75.3  191  47.2  41 | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 4.91% w/v | 1.44% w/v  (-70.7%) | | **Sodium chlorate content** | 0.40% w/v | 1.43% w/v | | **Ratio sodium chlorate/av chlorine** | 8.1% w/w | 99.3% w/w | | **Appearance** | Transparent yellow slightly viscous liquid. White particles are observed after storage. | | | **pH 1% at 20°C** | 12.2 | 12.1 | | **Alcalinity/Acidity** | 8.4 | 7.0 | | **Dilution stability**  (at 4% w/v) | Presence of a deposit at the bottom of the flask after 18h | No residues after 18h (the bottom of the flask is cloudy) | | **Persistent foam**  (at 4% w/v) | 173 mL after 1min | 173 mL after 1min |   Applicant: Significant decrease of the active substance content (-71%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)  CIPAC MT 75.3  191  47.2  41 | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | The sample was stored at ambient temperature (20°C) in 1L HDPE bottle   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | **Initial** | **After 3 months**  **opaque HDPE** | **After 4 months**  **opaque HDPE** | **After 5 months**  **opaque HDPE** | **After 6 months**  **opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 4.91% w/v | 4.02% w/v  (-18.1%) | 4.42% w/v  (-10.0%) | 4.50% w/v  (-8.4%) | 3.99% w/v  (-18.7%) | | **Sodim chlorate content** | 0.40% w/v | 0.69% w/v | 0.76% w/v | 0.84% w/v | 0.93% w/v | | **Ratio sodium chlorate/av chlorine** | 8.1% w/w | 17.2% w/w | 17.2% | 18.7% w/v | 23.3% | | **Appearance** | Product: Transparent yellow slightly viscous liquid.  Packaging: No crack, no swelling, no color change. | | | | | | **pH 1% at 20°C** | 12.2 | Not determined | 12.1 | Not determined | 12.1 | | **Alcalinity/Acidity** | 8.4 | Not determined | 7.2 | Not determined | 7.3 | | **Dilution stability**  (at 4% w/v) | Presence of a deposit at the bottom of the flask after 18h | | | | | | **Persistent foam**  (at 4% w/v) | 171 mL after 1min | Not determined | 171 mL after 1min | Not determined | 178 mL after 1min |   Applicant: Significant decrease of the active substance content (-18%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 6-month storage at ambient temperature. There is no significant change in the other technical properties.  Therefore, to set a shelf life, data on efficacy and degradation products must be available.  Efficacy is demonstrated after 6-month storage (equivalent to a degradation of 18% of AS). See section 2.2.5.5. The sodium chlorate content after 5-month storage is taken into account for the risk assessment for human and environment.  Provided those explanations are considered appropriate, a shelf life of 6 months could be provided. | Y | Peysson, W. (2020)  Report RRCo-000381\_01 | The content of active chlorine decreases by more than 10%.  The ratio sodium chlorate/av chlorine always exceeds the limit of 5.4%. Refer to human health section regarding conclusion on chlorate content.According to efficacy section, the product remains efficious up to 6 months. A shelf life of 5 months is acceptable (to be in accordance with the other product of this SPC).  Other properties and compatibility with HDPE are acceptable. The pH remains also higher than 11 after storage, which is important to stabilize the active ingredient.  For persistent foaming, please refer to the relevant endpoint. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | 171 mL of foam is observed after 1 min at the concentration 4% w/v (8g in 200mL of water). The maximum level at this use rate is around 190mL after 1min.  Applicant: The level of foam generated exceed 60 ml after 1 min however no unacceptable risk to operators is expected since the formulation will be used only by professionals for which protection equipment are recommended. | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | Product if a foaming formulation. The volume of foam exceeds the maximum limits of 60mL after 1 min. However, foaming is a property of interest for this type formulation(in order to increase of contact time and to see where the product has been applied (especially for surfaces like walls). Additionally, the users are only professionals and specific protection equipments are recommended for spraying application. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC. Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | CIPAC MT 41 | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 18G002910 | At 4% m/v concentration, after 18h, a slight deposit and micelles are observed at the bottom of the flask. | Y | Peysson, W. (2019)  Report RRCo-000325\_01 | Acceptable. Residues consist of particles in suspension and micelles. No specific concern is expected during the application. |
| Surface tension | OECD 115 EU A.5 (ring method) | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  Batch 26200918001 | Pure test item: 32.3 mN/m at 19.9°C.  The test item was considered as surface-active. | Y | Demangel, B. (2019), Report No. 18-918046-002 | Acceptable. The product is surface active. |
| Viscosity | OECD 114 (viscometer with rotational spindles) | **OXE ALCA CHLORE MOUSSANT** 5% of active chlorine  26200918001 | The mean dynamic viscosity of the test item was   * With increasing gradient at 20°C: 40.5 (70 rpm) to 39.7 mPa.s (200 rpm) * With decreasing gradient at 20°C: 45.5 mPa.s (70 rpm) to 44.2 mPa.s (200 rpm) * With increasing gradient at 40C: 37.3 mPa.s (70 rpm) to 38.3 mPa.s (200 rpm) * With decreasing gradient at 40°C: 37.2 mPa.s (70 rpm) to 36.2 mPa.s (200 rpm) | Y | Demangel, B. (2019), Report No. 18-918046-002 | Acceptable. The product is a newtonian fluid. |

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| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 1** |
| The formulations **OXE** **ALCA** and **OXE ALCA CHLORE MOUSSANT** are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of **OXE** **ALCA** is that of transparent yellow liquid. The appearance of **OXE** **ALCA** **CHLORE MOUSSANT** is that of transparent yellow slightly viscous liquid.  The stability of both formulations was not demonstrated after storage 2 weeks at 54°C, the active chlorine content decreased strongly (up to -70%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation OXE ALCA was not fully demonstrated after storage 5 months at ambient temperature, the active chlorine content decreased significantly (-18%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content.  The stability of the formulation OXE ALCA CHLORE MOUSSANT was not demonstrated after storage 6 months at ambient temperature, the active chlorine content decreased significantly (-19%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content.  Refer to human health section regarding conclusion on chlorate content.  Efficacy of these products has been demonstrated after 6 months. Therefore, a shelf life of 5 months can be granted for this meta SPC (no information is available after 6 months regarding NaOCl content, chlorate content and physical chemical properties).  Compatibility of the products with HDPE is acceptable.  The volume of foam for OXE ALCA MOUSSANT can exceed the limit of 60mL after 1 min.  **Implication concerning labelling for the products of meta SPC 1:**  Shelf life: 5 months  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  EUH031 “contact with acids liberates toxic gas”  Products should not be used in conjunction with acids or ammonia. |

Meta-SPC 2 – Bleach 9.6 - 12.5% professional:

Formulations supported in the Meta SPC 2 are JAVEL 12.5 PRO OXENA and JAVEL 9.6 PRO OXENA, both formulations are Soluble Concentrate (SL). Assessment of physical, chemical and technical properties of formulations JAVEL 12.5% is presented below. As the only difference between those two formulations is the active substance content, and as JAVEL 12.5 could be considered as a worst-case due to its higher active chlorine content, the physical, chemical and technical properties, as well as the shelf life of JAVEL 9.6 were not studied but considered as covered by the assessment of JAVEL 12.5.

**JAVEL 12,5 PRO OXENA**

The biocidal product is a Soluble Concentrate formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine  Batch 18G002052 | Transparent slightly yellow liquid. | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine Batch 18G002052 | Typical smell of chlorine. | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **JAVEL 12.5 PRO OXENA** 12.5%w/w of active chlorine Batch 18G002052 | pH of 1% dilution at 19.3°C : 11.6 | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | Acceptable. Neat pH is not available. However it is expected to be >11.5 as diluted pH is 11.6. |
| Acidity / alkalinity | CIPAC MT 191 | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine Batch 18G002052 | Alkalinity: 7.4% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | Acceptable |
| Relative density / bulk density | OECD 109 (pycnometer method) | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine  Batch 18D001872 | Density: 1.2106 g/mL (mean of two determinations) | Y | Peysson, W. (2019)  Report RRCo-000354\_01 | Acceptable |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)  CIPAC MT 46.3  75.3  191  47.2  41 | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine  Bathc 18G002052 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 13.61% w/v | 2.16% w/v  (-70.7%) | | **Sodium chlorate content** | 1.32% w/v | 6.38% w/v | | **Ratio sodium chlorate/av chlorine** | 9.7% w/w | 295% w/w | | **Appearance** | Transparent slightly yellow liquid. White particules are observed after storage. | | | **pH 1% at 20°C** | 11.6 | 11.6 | | **Alcalinity/Acidity** | 7.4 | 2.4 | | **Dilution stability**  (1.5% w/v) | Presence of supernatant particles and micelles (white cloud) in the bottom of the flask | Presence of micelles (white cloud) in the bottom of the flask | | **Persistent foam**  (1.5% w/v) | 0 mL after 1 min | 0 mL after 1 min |   Applicant: Significant decrease of the active substance content (-71%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  41 | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine  Batch 18G002052 | The sample was stored at ambient temperature (20°C) in 5L HDPE bottle, in darkness   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 3 months**  **opaque HDPE** | **After 4 months**  **opaque HDPE** | **After 5 months**  **opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 13.61% w/v | 8.2% w/v  (-39.8%) | 8.79% w/v  (-35.4%) | 8.28% w/v  (-39.2%) | | **Sodium chlorate content** | 1.32% w/v | 2.6% w/v | 3.49% w/v | 4.08% w/v | | **Ratio sodium chlorate/av chlorine** | 9.7% w/w | 31.7% w/w | 39.7% w/w | 49.3% w/w | | **Appearance** | Product: Transparent yellow liquid with typical odour of chlorine  Packaging: No crack, no swelling, no colour change. | | | | | **pH 1% at 20°C** | 11.6 | 11.5 | 11.4 | Not determined | | **Alcalinity/Acidity** | 7.4% | 4.3% | 3.9% | Not determined | | **Dilution stability**  **(1.5% w/v)** | Presence of white supernatant and slight deposit after 18h | | | Not determined | | **Persistent foam**  **(1.5% w/v)** | 0 mL after 1 min | 0 mL after 1 min | 0 mL after 1 min | Not determined | |  |  |  |  |  |   Applicant: Significant decrease of the active substance content (-39%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 5 months storage at ambient temperature. There is no significant change in the other technical properties.  Therefore, to set a shelf life, data on efficacy and degradation products must be available.  Efficacy is demonstrated after 5-month storage (equivalent to a degradation of 39% of AS). See section 2.2.5.5. The sodium chlorate content after 5-month storage is taken into account for the risk assessment for human and environment.  Provided those explanations are considered appropriate, a shelf life of 5 months could be provided. | N | Peysson, W. (2019)  Report RRCo-000382\_01 | Final report is available (5 months). The content of active chlorine decreases by more than 10%.  The ratio sodium chlorate/av chlorine always exceeds the limit of 5.4%. Refer to human health section regarding conclusion on chlorate content. According to efficacy section, the product remains efficious up to 6 months. A shelf life of 5 months is acceptable.  Other properties and compatibility with HDPE are acceptable. The pH remains also higher than 11 after storage (also expected to be at this level after 5 months), which is important to stabilize the active ingredient. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine Batch 18G002052 | No foam is observed after 1 min at the concentration 1.5 % w/v. | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | The formulation is not a foaming product. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposed for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | CIPAC MT 41 | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine Batch 18G002052 | At 1.5% m/v concentration, after 18h, presence of supernatant particles and micelles are observed.  Applicant: Nevertheless, no blockage of the application equipment or unacceptable risk is expected since the formulation is not intented to be applied by spraying. | Y | Peysson, W. (2019)  Report RRCo-000326\_01 | According to the use claimed for meta SPC 2, spraying is one of the application method. However, the residues consist of particles in suspension and micelles. No specific concern is expected during the application. |
| Surface tension | OECD 115 EU A.5 (ring method) | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine  Batch 118D001872 | Pure test item: 65.9 mN/m at 20°C | Y | Demangel, B. (2019), Report No. 18-918046-003 | The test item is not considered as surface-active. |
| Viscosity | OECD 114 (viscometer with rotational spindles) | **JAVEL 12.5 PRO OXENA** 12.5% of active chlorine  Batch 118D001872 | The mean dynamic viscosity of the test item was   * At 20°C: from 2.62 to 2.88 mPa.s (30 to 180 RPM, increasing gradient), from 2.74 to 2.87 mPa.s (30 to 180 RPM, decreasing gradient), * At 40°C: 1.78 to 2.88 mPa.s (40 to 200 RPM, increasing gradient), 1.74 to 2.93 mPa.s (40 to 200 RPM, decreasing gradient) | Y | Demangel, B. (2019), Report No. 18-918046-003 | Acceptable. The product is a Newtonian fluid. |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 2** |
| The formulation **JAVEL 12.5** **PRO OXENA** is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of **JAVEL 12.5 PRO OXENA** is that of transparent yellow liquid.  The stability of the formulations was not demonstrated after storage 2 weeks at 54°C, the active chlorine content decreased strongly (-71%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation JAVEL 12.5 PRO OXENA was not demonstrated after storage 5 months at ambient temperature, as the active chlorine content decreased significantly (-40%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. Refer to human health section regarding conclusion on chlorate content. Physico chemical tests provided to JAVEL 12.5 PRO OXENA cover the whole Meta SPC 2. Indeed the second product JAVEL 9.6 PRO OXENA contains the same formulants and presents a lower content of active chlorine (9.6% w/w). Since the degradation of av chlorine content is faster at high concentrations, the shelf life of the product JAVEL 9.6 PRO OXENA will not be lower to the one of JAVEL 12.5 PRO OXENA.  Efficacy of these products has been demonstrated after 6 months. A shelf life of 5 months is acceptable for this meta SPC (information on NaOCl content, chlorate content and physical chemical properties are not available after 6 months).  Compatibility of the products with HDPE is acceptable.  Providing those explanations are considered appropriate, the shelf life of 5 months could be granted for products in Meta-SPC 2.  **Implication concerning labelling for the products of meta SPC2:**  Shelf life: 5 months  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”  Products should not be used in conjunction with acids or ammonia. |

**META SPC 3 – BLEACH 2.6% PROFESSIONAL**

Formulations supported in the Meta SPC 3 are Javel 2.6 détergence PRO OXENA, Javel 2.6 détergence citron PRO OXENA, Javel 2.6 détergence pin PRO OXENA, Javel 2.6 détergence eucalyptus PRO OXENA, Javel 2.6 PRO OXENA, Javel 2.6 eucalyptus PRO OXENA, Javel 2.6 citron PRO OXENA. All formulations are Soluble Concentrate (SL).

Assessment of physical, chemical and technical properties of formulations JAVEL 2.6 PRO/GP OXENA, JAVEL 2.6 CITRON PRO/GP OXENA and JAVEL 2.6 DÉTERGENCE CITRON PRO OXENA is presented below.

As the only difference between JAVEL 2.6 CITRON PRO/GP OXENA and JAVEL 2.6 EUCALYPTUS PRO/GP OXENA is the perfume; the physical, chemical and technical properties, as well as the shelf-life of JAVEL 2.6 EUCALYPTUS PRO/GP OXENA were not studied but considered as covered by the assessment of JAVEL 2.6 CITRON PRO/GP OXENA.

As the only difference between Javel 2.6 détergence, Javel 2.6 détergence pin, Javel 2.6 détergence citron and Javel 2.6 détergence eucalyptus is the perfume, the physical, chemical and technical properties, as well as the shelf life of Javel 2.6 détergence, Javel 2.6 détergence pin, Javel 2.6 détergence eucalyptus were not studied but considered as covered by the assessment of Javel 2.6 détergence citron. Please refer to confidential annex regarding read across for products with perfumes.

**JAVEL 2.6 PRO/GP OXENA**

The biocidal product is a Soluble Concentrate formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | Transparent slightly yellow liquid. | Y | Peysson, W. (2019)  Report RRCo-000327\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | Typical smell of chlorine. | Y | Peysson, W. (2019)  Report RRCo-000327\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | pH of 1% dilution at 19.3°C : 10.5 | Y | Peysson, W. (2019)  Report RRCo-000327\_01 | Acceptable. Neat pH is not available. However diluted pH is 10.5. Without further measurement, eCA considers that neat pH is expected to be >11.5. |
| Acidity / alkalinity | CIPAC MT 191 | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | Alkalinity: 1.3% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000327\_01 | Acceptable |
| Relative density / bulk density | - | **-** | - | - | - | Relative density is missing. However, based on the composition and read across with product JAVEL 2.6 CITRON PRO/GP (meta SPC 3), a relative density of 1-1.1 is expected. |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 46.3  75.3  191  47.2  41 | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 2.96% w/v | 2.38% w/v  (-24.4%) | | **Sodium chlorate content** | 0.06% w/v | 0.37% w/v | | **Ratio sodium chlorate/av chlorine** | 2% w/w | 15.6% w/w | | **Appearance** | Transparent slightly yellow liquid. Particules are observed after storage. | | | **pH 1% at 20°C** | 10.5 | 10.5 | | **Alcalinity/Acidity** | 1.3 | 1.0 | | **Dilution stability**  (7% w/v) | Presence of supernatant particles | Presence of supernatant particles and some micelles in the bottom of the flask | | **Persistent foam**  (7% w/v) | 0 mL after 10s | 0 mL after 10s |   Applicant: Significant decrease of the active substance content (-24.4%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2020)  Report RRCo-000383\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  41 | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | The sample was stored at ambient temperature (20°C) in 1L HDPE bottle   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 6 months in**  **opaque HDPE** | **After 9 months in opaque HDPE** | **After 1 year in opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 2.96 % w/v | 2.71% w/v  (-8.4%) | 2.74 % w/v  (-7.4%) | 2.88 % w/v  (-2.9%) | | **Sodim chlorate content** | 0.06% w/v | 0.10% w/v | 0.13% w/v | 0.14% w/v | | **Ratio sodium chlorate/av chlorine** | 2% w/w | 3.7% w/w | 4.7% w/w | 4.9% w/w | | **Appearance** | Product: Transparent slightly yellow liquid, bleach odour  Packaging: No crack, no swelling, no change of colour | | | | | **pH 1% at 20°C** | 10.5 | 10.2 | 9.9 | 9.8 | | **Alcalinity/Acidity** | 1.3% | 1.2% | 1.5% | 1.1% | | **Dilution stability**  (7% w/v) | Presence of supernatant particles | | | | | **Persistent foam**  (7% w/v) | 0 mL after 10s | 0 mL after 10s | 0 mL after 10s | 0 mL after 10s |   Applicant: No significant change is observed neither in the active substance content nor in sodium chlorate content, which remains below the acceptable limit of 5.4% of active chlorine content. There is no significant change in the physical and chemical properties of the formulation. The formulation is stable after 1-year storage at ambient temperature. | N (mid term report) | Peysson, W. (2020)  Report RRCo-000383\_01 | The content of active chlorine has decreased but variations remain below 10% after 1 year.  The ratio sodium chlorate/av chlorine always remains below the limit of 5.4% after 1 year. Refer to human health section regarding conclusion on chlorate content.  Other properties and compatibility with HDPE are acceptable. The pH remains stable upon storage.  The product can be considered stable up to 1 year at ambient temperature in HDPE packaging.  Persistent foaming was not given after 1 min. However cross reading with JAVEL 12.5 PRO OXENA (meta SPC2) is possible due to similar composition. As this product does not form foam, it can be assumed that it is also the case for product JAVEL 2.6 PRO/GP OXENA. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | No foam is observed after 10s at the concentration 7 % w/v. | Y | Peysson, W. (2019)  Report RRCo-000327\_01 | Persistent foaming was not given after 1 min. However cross reading with JAVEL 12.5 PRO OXENA (meta SPC2) is possible due to similar composition. As this product does not form foam, it can be assumed that it is also the case for product JAVEL 2.6 PRO/GP OXENA. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Note that for products with a content of active substance <5% w/w, mention EUH031 is not necessary. Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | CIPAC MT 41 | **JAVEL 2.6 PRO/GP OXENA**  2.6% of active chlorine  Batch 18M001902 | At 7% m/v concentration, after 18h, supernatant particules are observed.  Applicant: Nevertheless, no blockage of the application equipment or unacceptable risk is expected since the formulation is not intented to be applied by spraying. | Y | Peysson, W. (2019)  Report RRCo-000327\_01 | Spraying is a possible application method for meta SPC 3. However, surpenatant particles are not expected to be a significant concern for nozzles. No further data are deemed necessary. |
| Surface tension | - | **-** | - | - | - | Surface tension was not provided. However cross reading with JAVEL 12.5 PRO OXENA (meta SPC2) is possible due to similar composition. The product is not expected to be surface active (i.e >60 mN/m). |
| Viscosity | - | **-** | - | - | - | Viscosity was not provided. However cross reading with JAVEL 12.5 PRO OXENA (meta SPC 2) is possible due to similar composition. The magnitude for JAVEL 2.6 PRO/GP OXENA should be 1-3 mPa.s. |

**JAVEL 2.6 CITRON PRO/GP OXENA**

The biocidal product is a Soluble Concentrate formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | Transparent slightly yellow liquid. | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | Smell of lemon bleach | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | pH of 1% dilution at 19.3°C : 10.4 | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | Acceptable. Neat pH is not available. However diluted pH is 10.4. Without further measurement, eCA considers that neat pH is expected to be >11.5. |
| Acidity / alkalinity | CIPAC MT 191 | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | Alkalinity: 1.3% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | Acceptable |
| Relative density / bulk density | OECD 109 (pycnometer method) | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18001321 | Density: 1.0333 g/mL (mean of two determinations) | Y | Peysson, W. (2019)  Report RRCo-000355\_01 | Acceptable.  Relative density for other products named “JAVEL 2.6 XXX PRO OXENA” have similar composition (only perfumes are changing) and results are assumed to be identical. |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 46.3  75.3  191  47.2  41 | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 2.93 % w/v | 2.15 % w/v  (-26.6%) | | **Sodim chlorate content** | 0.06% w/v | 0.34% w/v | | **Ratio sodium chlorate/av chlorine** | 2% w/w | 15.8% w/w | | **Appearance** | Transparent slightly yellow liquid. Particules are observed after storage. | | | **pH 1% at 20°C** | 10.4 | 10.1 | | **Alcalinity/Acidity** | 1.3 | 0.9 | | **Dilution stability**  (at 7% w/v) | Presence of supernatant particles | Presence of supernatant particles | | **Persistent foam**  (7% w/v) | 79.1 mL after 1min | 0 mL after 1 min |   Applicant: Significant decrease of the active substance content (-26.6%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  41 | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | The sample was stored at ambient temperature (20°C) in 1L HDPE bottle   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 6 months in**  **opaque HDPE** | **After 9 months in opaque HDPE** | **After 1 year in opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 2.93% w/v | 2.77% w/v  (-5.5%) | 2.70% w/v  (-7.8%) | 2.69% w/v  (-8.2%) | | **Sodium chlorate content** | 0.06% w/v | 0.10% w/v | 0.12% w/v | 0.14% w/v | | **Ratio sodium chlorate/av chlorine** | 2.1% w/w | 3.6% w/w | 4.4% w/w | 5.2% w/w | | **Appearance** | Product. Transparent slightly yellow liquid.  Packaging: no crack, no swelling, no change of colour | | | | | **pH 1% at 20°C** | 10.4 | 9.8 | 9.6 | 9.8 | | **Alcalinity/Acidity** | 1.3% | 1.2% | 1.4% | 1.0% | | **Dilution stability** | Presence of supernatant particles | | | | | **Persistent foam**  (7% w/v) | 79 mL after 1min | 71 mL after 1 min | 65 mL after 1min | 30 mL after 1 min |   Applicant: No significant change is observed neither in the active substance content nor in sodium chlorate content, which remains below the acceptable limit of 5.4% of active chlorine content. There is no significant change in the physical and chemical properties of the formulation. The formulation is stable after 1-year storage at ambient temperature. | Y | Peysson, W. (2020)  Report RRCo-000384\_01 | The content of active chlorine has decreased but variations remain below 10% after 1 year.  The ratio sodium chlorate/av chlorine always remains below the limit of 5.4% after 1 year. Refer to human health section regarding conclusion on chlorate content.  Other properties and compatibility with HDPE are acceptable. The pH remains stable upon storage.  The product can be considered stable up to 1 year at ambient temperature in HDPE packaging.  For persistent foaming, see conclusion in the relevant endpoint. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be kept at a temperature below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | 79 mL of foam is observed after 1 min at the concentration 7% w/v (14g in 200mL of water). The maximum volume of foam produced at this use rate is around 90mL after 10s.  Applicant: The level of foam generated exceed 60 ml after 1 min however no unacceptable risk to operators is expected since the formulation will be used only by professionals for which protection equipment are recommended. | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | The volume of foam exceeds the maximum limits of 60mL after 1 min. However, foaming may be a property of interest for this type formulation (in order to increase of contact time and to see where the product has been applied, especially for surfaces like walls,…). Additionally specific protection equipments are recommended for spraying application (only professional users for meta SPC 3). |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Note that for products with a content of active substance <5% w/w, mention EUH031 is not necessary.  Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | CIPAC MT 41 | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18G001902 | At 7% m/v concentration, after 18h, supernatant particules are observed.  Applicant: Nevertheless, no blockage of the application equipment or unacceptable risk is expected since the formulation is not intented to be applied by spraying. | Y | Peysson, W. (2019)  Report RRCo-000328\_01 | Spraying is a possible application method for meta SPC 3. However, surpenatant particles are not expected to be a significant concern for nozzles. No further data are deemed necessary. |
| Surface tension | OECD 115 EU A.5 (ring method) | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18001321 | Pure: 29.5 mN/m at 19.8°C | Y | Demangel, B. (2019), Report No. 18-918046-004 | Acceptable. The test item is considered as surface-active.  Surface tension for other products named “JAVEL 2.6 XXX PRO OXENA” have similar composition (only perfumes are changing) and results are assumed to be identical. |
| Viscosity | OECD 114 (viscometer with rotational spindles) | **JAVEL 2.6 CITRON PRO/GP OXENA**  2.6% of active chlorine  Batch 18001321 | The dynamic viscosity of the test item was ranging from   * At 20°C: 1.32 mPa.s at 50RPM to 1.29mPA.s at 90RPM (increasing gradient) and from 1.37 mPa.s at 50RPM to 1.32 RPM at 90RPM (decreasing gradient)   Applicant: It was not possible to obtain results at 40.0 °C as the results were lower than 1.0 mPa.s (limit of reliability of the values). | Y | Demangel, B. (2019), Report No. 18-918046-004 | Acceptable. Based on the results, the product is considered as a Newtonian fluid.  Viscosity for other products named “JAVEL 2.6 XXX PRO OXENA” have similar composition (only perfumes are changing) and results are assumed to be identical. |

**JAVEL 2.6 DETERGENCE CITRON PRO/GP OXENA**

The biocidal product is a Soluble Concentrate (SL) formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | Transparent slightly yellow liquid. | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | Lemon bleach odour. | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | pH of 1% dilution at 19.3°C : 10.9 | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | Acceptable. Neat pH is not available. However diluted pH is 10.9. As the product contains NaOH, eCA considers that neat pH is expected to be >11.5. |
| Acidity / alkalinity | CIPAC MT 191 | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | Alkalinity: 1.5% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | Acceptable |
| Relative density / bulk density | OECD 109 (pycnometer method) | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6%  of active chlorine  batch 18001249 | Density: 1.0521 g/mL at 20°C (mean of two determinations) | Y | Peysson, W. (2019)  Report RRCo-000356\_01 | Acceptable. Density for other products named “JAVEL 2.6 DETERGENCE XXX PRO OXENA” have similar composition (only perfumes are changing) and results are assumed to be identical. |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 46.3  75.3  191  47.2  41 | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 2.42 % w/v | 0.18 % w/v  (-92.6%) | | **Sodium chlorate content** | 0.03% w/v | 0.18 % w/v | | **Ratio sodium chlorate/av chlorine** | 1.2% w/w | 100% w/w | | **Appearance** | Transparent viscous slightly yellow liquid. Typical smell of lemon bleach. Cloudy white liquid after storage. | | | **pH 1% at 20°C** | 10.9 | 9.9 | | **Alcalinity/Acidity** | 1.5 | 0.4 | | **Dilution stability**  (8% w/v) | No residues | Cloudy solution | | **Persistent foam**  (8% w/v) | 171 mL after 1min | 143 mL after 1min |   Applicant: Significant decrease of the active substance content (-92.6%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  41 | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | The sample was stored at ambient temperature (20°C) in 1L HDPE bottle, in darkness   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 6 months in**  **opaque HDPE** | **After 9 months in**  **opaque HDPE** | **After 1 year in opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 2.42 % w/v | 2.03 % w/v  (-16.1%) | 2.0 % w/v  (-17.4%) | 1.83 % w/w  (-24.4%) | | **Sodium chlorate content** | 0.03% w/v | 0.06% w/v | 0.07% w/v | 0.09% w/w | | **Ratio sodium chlorate/av chlorine** | 1.24% w/w | 2.9% w/w | 3.5% w/w | 4.9% w/w | | **Appearance** | Product: transparent, viscous liquid, slightly yellow, typical smell of lemon bleach  Packaging: no crack, no swelling, no change of colour | | | | | **pH 1% at 20°C** | 10.9 | 10.7 | 10.9 | 10.2 | | **Alcalinity/Acidity** | 1.5% | 1.2% | 1.3% | 0.9% | | **Dilution stability**  (8%w/v) | No residues (cloudy solution after 6, 6 and 12 months) | | | | | **Persistent foam after 1min**  (8% w/v) | 173 mL | 176 mL | 172 mL | 96 mL |   Applicant: Significant decrease of the active substance content (-24%) is observed after 1 year storage at ambient temperature. The sodium chlorate remains below the acceptable limit of 5.4% of active chlorine content are  Therefore, to set a shelf life, data on efficacy must be available.  Efficacy is demonstrated after 12-month storage (equivalent to a degradation of 24% of AS). See section 2.2.5.5.  Provided those explanations are considered appropriate, a shelf life of 12 months could be provided. | N (mid intermim report) | Peysson, W. (2020)  Report RRCo-000385\_01 | Variations of active substance content are higher than 10% after 1 year.  The ratio sodium chlorate/av chlorine does not exceed the limit of 5.4% after 1 year. Refer to human health section regarding conclusion on chlorate content. Efficacy of the product has been demonstrated after 12 months. A shelf life of 12 months is therefore acceptable.  Other properties and compatibility with HDPE are acceptable. The pH remains stable upon storage.  For persistent foaming, see conclusion in the relevant endpoint. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be kept below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | 173 mL of foam is observed after 1 min at the concentration 8% w/v (16g of product in 200mL of water).  The maximum volume obtained at such use rate is 195mL of foam after 10s.  Applicant: The level of foam generated exceed 60 ml after 1 min however no unacceptable risk to operators is expected since the formulation will be used only by professionals for which protection equipment are recommended. | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | The volume of foam exceeds the maximum limits of 60mL after 1 min. The product is a foaming formulation. However, foaming may be a property of interest for this type formulation (in order to increase of contact time and to see where the product has been applied, especially for surfaces like walls,…). Additionally specific protection equipments are recommended for spraying application (only professional users for meta SPC 3). |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Note that for products with a content of active substance <5% w/w, the mention EUH031 is not necessary. |
| Dilution stability | CIPAC MT 41 | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18G001990 | At 8% m/v concentration, after 18h, the solution is cloudy.  Applicant: Nevertheless, no blockage of the application equipment or unacceptable risk is expected since the formulation is not intented to be applied by spraying. | Y | Peysson, W. (2019)  Report RRCo-000329\_01 | Acceptable.  Note that spraying is a possible application method for this meta SPC according to the uses claimed. |
| Surface tension | EU A.5 (plate method) | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18001249 | Pure test item: 27.6 mN/m at 19.9°C | Y | Demangel, B. (2019), Report No. 18-918046-005 | Acceptable. The test item is considered as surface-active.  Surface tension for other products named “JAVEL 2.6 DETERGENCE XXX PRO OXENA” have similar composition (only perfumes are changing) and results are assumed to be identical. |
| Viscosity | OECD 114 (viscometer with rotational spindles) | **Javel 2.6 détergente citron** **PRO/GP OXENA** 2.6% of active chlorine  Batch 18001249 | The mean dynamic viscosity of the test item was   * At 20°C: ranging from 750mPa.s to 65 mPa.s (4.5 to 200 RPM, increasing gradient) and 729 to 65 mPa.s (4.5 to 200 RPM, decreasing gradient) * At 40°C: ranging from 83 to 66 mPa.s (40 to 200 RPM, increasing gradient or decreasing gradient) | Y | Demangel, B. (2019), Report No. 18-918046-005 | Acceptable. The product is not a Newtonian fluid.  Viscosity for other products named “JAVEL 2.6 DETERGENCE XXX PRO OXENA” have similar composition (only perfumes are changing) and results are assumed to be identical. |

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| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 3** |
| The formulations **JAVEL 2.6 PRO/GP OXENA, JAVEL 2.6 CITRON** **PRO/GP OXENA** and **JAVEL 2.6 DÉTERGENTE CITRON PRO OXENA** are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of these formulationsis that of transparent yellow liquid.  The stability of the formulations was not demonstrated after storage 2 weeks at 54°C, the active chlorine content decreased strongly (-24.4%, -26.6% and -93.6% respectively) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation JAVEL 2.6 DÉTERGENTE CITRON PRO OXENA was not demonstrated after storage 12 months at ambient temperature, the active chlorine content decreased significantly (-24.4%) while the sodium chlorate content was found below the maximum limit of 5.4% of the active chlorine content. Refer to human health section regarding conclusion on chlorate content. However, the efficacy is demonstrated after 12 months.  The stability of the formulation JAVEL 2.6 PRO/GP OXENA, JAVEL 2.6 CITRON PRO/GP OXENA was demonstrated after storage 12 months at ambient temperature.  Compatibility of the products with HDPE is acceptable.  The volume of foam can exceed the limit of 60mL after 1 min for some producs of this meta SPC.  The three products tested are representative of the whole meta SPC 3. Compositions of the other products of this meta SPC are similar and the only difference is related to the perfumes added. Extrapolation is considered acceptable. Please refer to confidential annex regarding the read across for products with perfumes.  Providing those explanations are considered appropriate, the shelf life of 12 months could be granted for products in Meta-SPC 3.  **Implication concerning labelling for the products of meta SPC 3:**  Shelf life: 12 months  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products.  Products should not be used in conjunction with acids or ammonia. |

**META SPC 4 – BLEACH 2.6% NON-PROFESSIONAL**

Formulations supported in the Meta SPC 4 are JAVEL 2.6 GP OXENA, JAVEL 2.6 PIN GP OXENA, JAVEL 2.6 EUCALYPTUS GP OXENA, JAVEL 2.6 LAVANDE GP OXENA, JAVEL 2.6 CITRON GP OXENA, all formulations are Soluble Concentrate (SL).

Assessment of physical, chemical and technical properties of the formulation Javel 2.6 PRO/GP OXENA and Javel 2.6 CITRON PRO/GP OXENA is presented under Meta-SPC 3.

As the only difference between JAVEL 2.6 CITRON GP OXENA, JAVEL 2.6 PIN, JAVEL 2.6 EUCALYPTUS GP OXENA and JAVEL 2.6 LAVANDE GP OXENA is the perfume the physical, chemical and technical properties, as well as the shelf-life of JAVEL 2.6 PIN GP OXENA, JAVEL 2.6 EUCALYPTUS GP OXENA and JAVEL 2.6 LAVANDE GP OXENA were not studied but considered as covered by the assessment of JAVEL 2.6 CITRON GP OXENA, presented under Meta SPC 3. Please refer to confidential annex regarding the read across for products with perfumes.

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| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 4** |
| The formulations **JAVEL 2.6 PRO/GP OXENA** and **JAVEL 2.6 CITRON** **PRO/GP OXENA** are soluble concentrate formulations. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of these formulationsis that of transparent yellow liquid.  The stability of the formulations was not demonstrated after storage 2 weeks at 54°C, the active chlorine content decreased strongly (-24.4% and -26.6% respectively) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation JAVEL 2.6 PRO/GP OXENA, JAVEL 2.6 CITRON PRO/GP OXENA was demonstrated after storage 12 months at ambient temperature, the shelf life of 12 months could be granted for products in Meta-SPC 4.  Compatibility of the products with HDPE is acceptable.  The volume of foam can exceed the limit of 60 mL after 1 min for some products. Products are foaming formulation.  The two products tested are representative of the whole meta SPC4. Compositions of the other products of this meta SPC are similar and the only difference is related to the perfumes added. Extrapolation is considered acceptable. Please refer to confidential annex regarding the read across for products with perfumes.  Providing those explanations are considered appropriate, the shelf life of 12 months could be granted for products in Meta-SPC 4.  **Implication concerning labelling for the product of meta SPC 4:**  Shelf life: 12 months  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Foaming products  EUH 206: Warning! Do not use together with other products. May release dangerous gases (chlorine) (non professional use).  Products should not be used in conjunction with acids or ammonia. |

**META SPC 5 – ANTI LICHEN PROFESSIONAL**

Formulations supported in the Meta SPC 5 are EXTIMUM (Javel 6), Javel 6 pin, Javel 6 eucalyptus, Javel 6 lavande, Javel 6 citron, all formulations are Soluble Concentrate (SL).

As the only difference between Extimum (Javel 6), Javel 6 pin, Javel 6 eucalyptus, Javel 6 lavande and Javel 6 citron is the perfume, the physical, chemical and technical properties, as well as the shelf-life of Extimum (Javel 6), Javel 6 pin, Javel 6 lavande and Javel 6 citron were not studied but considered as covered by the assessment of Javel 6 eucalyptus. Please refer to confidential annex regarding the bridging for products with perfumes.

**JAVEL 6 EUCALYPTUS**

The biocidal product is a Soluble Concentrate (SL) formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **Javel 6 eucalyptus**  6% of active chlorine  Batch 26031219001 | Transparent yellow liquid. | N (mid term report) | Peysson, W. (2020)  Report RRCo-000614\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **Javel 6 eucalyptus**  6% of active chlorine  Batch 26031219001 | Resin smell | N (mid term report) | Peysson, W. (2020)  Report RRCo-000614\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **Javel 6 eucalyptus**  6% of active chlorine  Batch 26031219001 | pH of 1% dilution at 19.3°C : 11.9 | N (mid term report) | Peysson, W. (2020)  Report RRCo-000614\_01 | Acceptable. Neat pH is not available. However as diluted pH is 11.9, neat pH is expected to be >11.5. |
| Acidity / alkalinity | CIPAC MT 191 | **Javel 6 eucalyptus**  6% of active chlorine  Batch 26031219001 | Alkalinity: 5.11% as NaOH | N (mid term report) | Peysson, W. (2020)  Report RRCo-000614\_01 | Acceptable |
| Relative density / bulk density | - | **-** | Not determined  1.13 (declared by the applicant) | - | - | Acceptable. Density is consistent with the one of the other products of the family. |
| Storage stability test – **accelerated storage** |  |  | Not performed |  |  | Acceptable since the active ingredient is sensitive to heat. The product should be kept at ambient temperature. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  179 | **Javel 6 eucalyptus**  6% of active chlorine  Batch 26031219001 | The sample was stored at ambient temperature in 5L HDPE bottle, in darkness   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 2 months in**  **opaque HDPE** | **After 6 months in opaque HDPE** | **After 8 months in opaque HDPE** | | **Active ingredient content** (total active chlorine  decrease) | 6.53 % w/v | 5.77% w/v  (-11.6%) | 4.97% w/v  (-23.9%) | 4.6% w/v  (-29.6%) | | **Sodium chlorate content** | 0.15 % w/v | 0.35 % w/v | 0.62% w/v | 0.75% w/v | | **Ratio sodium chlorate/av chlorine** | 2.3% w/w | 6.1% | 12.5% | 16.3% | | **Appearance** | Product: Transparent yellow liquid with typical chlorine odour.  Packaging: No crack, no swelling, no change of colour. | | | | | **pH 1% at 20°C** | 11.9 | 11.9 | 11.92 | 11.88 | | **Alcalinity/Acidity** | 5.11% | 5.05% | 4.79 | 4.43 |   Applicant: Significant decrease of the active substance content (-11.6%) is observed after 2-month storage at ambient temperature. The sodium chlorate exceed the acceptable limit of 5.4% of active chlorine content.  Therefore, to set a shelf life, data on efficacy and degradation products must be available.  Efficacy is demonstrated after 2-month storage (equivalent to a degradation of 11.6% of AS). See section 2.2.5.5.  The sodium chlorate content after 5-month storage is taken into account for the risk assessment for human and environment.  Provided those explanations are considered appropriate, a shelf life of 2 months could be provided. | N (mid term report) | Peysson, W. (2020)  Report RRCo-000614\_01 | The content of active chlorine decreases by more than 10%.  The ratio sodium chlorate/av chlorine exceeds the limit of 5.4% after 8 months. Refer to human health section regarding conclusion on chlorate content. However, efficacy was not fully addressed for this meta SPC. Consequently, no shelf life can be set.  Other properties and compatibility with HDPE are acceptable. The pH remains also higher than 11 after storage, which is important to stabilize the active ingredient. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | - | **-** | Not relevant for a ready-to-use formulation | - |  | Not applicable since the product is ready to use. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. Mention EUH031 “contact with acids liberates toxic gas” is proposedfor this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | - | **-** | Not relevant for a ready-to-use formulation | - |  | Not applicable since the product is ready to use. |
| Surface tension | - | **-** | Not determined | - |  | No data was submitted for this meta SPC. However cross reading with product JAVEL 2.6 CITRON PRO OXENA of meta SPC 3 is possible. This product contains the same surfactants at a lower lowel and is surface active. Therefore, products of this meta SPC can also be regarded as surface active due to their composition. |
| Viscosity | - | **-** | Not determined | - |  | Viscosity is not available. However, according to the composition and results provided for other products of the family, viscosity is expected to similar to the one for water. |

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| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 5** |
| The formulation **JAVEL 6 EUCALYPTUS** is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of **JAVEL 6 EUCALYPTUS** is that of transparent yellow liquid.  The stability of the formulation was not tested after storage 2 weeks at 54°C. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation JAVEL 6 EUCALYPTUS was not demonstrated after storage 2, 6 and 8 months at ambient temperature, the active chlorine content decreased significantly (decrease higher than 10% of initial contentand the sodium chlorate content exceeds the maximum limit of 5.4% of the active chlorine content. Refer to human health section regarding conclusion on chlorate content. **However, the efficacy was not fully addressed for this meta SPC. Consequently, no shelf life can be set.**  Five products are claimed for this meta SPC. Compositions are similar and the only relevant change is related to the perfumes. Extrapolation is considered acceptable. Please refer to confidential annex regarding the read across for products with perfumes.  Compatibility of the products with HDPE is acceptable.  **Implication concerning labelling for the products of meta SPC 5:**  Shelf life: cannot be set due to a lack of efficacy data  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  EUH031 “contact with acids liberates toxic gas”.  Products should not be used in conjunction with acids or ammonia. |

**META SPC 6 BLEACH 4.8% NON PROFESSIONAL**

Formulations supported in the Meta SPC 6 are Javel 4.8, Javel 4.8 pin, Javel 4.8 eucalyptus, Javel 4.8 lavande and Javel 4.8 citron. All formulations are Soluble Concentrate (SL). Assessment of physical, chemical and technical properties of the formulation Javel 4.8 is presented below.

The only difference between Javel 4.8, Javel 4.8 pin, Javel 4.8 eucalyptus, Javel 4.8 lavande and Javel 4.8 citron is the perfume; the physical, chemical and technical properties were not studied but considered as covered by the assessment of Javel 4.8. However, the shelf life cannot be set based only on results obtained for Javel 4.8 since perfumes influence the degradation rate of active chlorine. Therefore, bridging with SPC 5 will be done due to similar composition. Please refer to confidential annex regarding the bridging for products with perfumes.

**Javel 4.8**

The biocidal product is a Soluble Concentrate formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | Transparent yellow liquid. | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | Typical smell of chlorine. | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | pH of 1% dilution at 19.3°C : 11.1 | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | Acceptable. Neat pH is not available. However as diluted pH is 11.1, eCA considers that neat pH is expected to be>11.5. |
| Acidity / alkalinity | CIPAC MT 191 | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | Alkalinity: 3.0% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | Acceptable |
| Relative density / bulk density | - | **-** | Not determined | - | - | Relative density is missing. However, based on the composition and read across with product JAVEL 2.6 CITRON PRO/GP (meta SPC 3), a relative density close to 1.1 is expected. |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 46.3  75.3  191  47.2  179 | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 5.38% w/v | 3.05% w/v  (-43.3%) | | **Sodium chlorate content** | 0.41% w/v | 1.49% w/v | | **Ratio sodium chlorate/av chlorine** | 7.6% w/w | 48.9% w/w | | **Appearance** | Transparent yellow liquid. | | | **pH 1% at 20°C** | 11.1 | 11.0 | | **Alcalinity/Acidity** | 3.0 | 2.4 | | **Dilution stability**  (at 5% w/v) | presence of white particles at the bottom of the flask after 18h | | | **Persistent foam**  (5% w/v) | 0 mL after 10s | 0 mL after 10s |   Applicant: Significant decrease of the active substance content (-43.3%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  179 | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | The sample was stored at ambient temperature (20°C) in 250 mL PVC berlingot   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 6 months in**  **PVC berlingot** | **After 9 months in PVC berlingot** | **After 1 year in PVC berlingot** | | **Active ingredient content** (total active chlorine decrease) | 5.38 % w/v | 5.01% w/v  (-6.88%) | 5.05% w/v  (-6.13%) | 4.92% w/v  (-8.55%) | | **Sodium chlorate content** | 0.41 % w/v | 0.78% w/v | 0.99% w/v | 1.04% w/v | | **Ratio sodium chlorate/av chlorine** | 7.6% w/w | 15.6% w/w | 19.6% w/w | 21.1% w/w | | **Appearance** | Product: Transparent yellow liquid with typical chlorine odour.  Packaging: No crack, no swelling, no change of colour. | | | | | **pH 1% at 20°C** | 11.1 | 10.9 | 11.5 | 10.9 | | **Alcalinity/Acidity** | 3.02% | 2.46% | 2.96% | 2.30% | | **Dilution stability**  **(at 5% w/v)** | presence of supernatant and deposit | | | | | **Persistent foam**  **(at 5% w/v)** | 0 mL after 1 min | 0 mL after 1 min | 0 mL after 1 min | 0 mL after 1 min | |  |  |  |  |  |   Applicant: No significant change is observed neither in the active substance content. However the sodium chlorate content is above the acceptable limit of 5.4% of active chlorine content. The sodium chlorate content after 1-year storage is taken into account for the risk assessment for human and environment.  There is no significant change in the physical and chemical properties of the formulation.  Provided those explanations are con-sidered appropriate, a shelf life of 12 months could be provided. | N (mid term report) | Peysson, W. (2019)  Report RRCo-000386\_01 | The content of active chlorine has decreased but variations remain below 10%.  However, the ratio sodium chlorate/av chlorine always exceeds the limit of 5.4%. Refer to human health section regarding conclusion on chlorate content. Products with perfume/surfactant are not covered by the tested product. A read across with SPC 5 can be done due to similar composition (worst case: more complex formulations and higher NaOCl content in SPC 5). A shelf life of 8 months could have been granted (based on the storage stability results obtained for SPC 5). However, variations after storage are always higher than 10% and efficacy is not demonstrated. Therefore no shelf life can be granted for products with perfume.  A shelf life of 12 months is only acceptable for JAVEL 4.8% as variations of active substance content are below 10%.  Other properties and compatibility with PVC berlingots are acceptable. Extrapolation to bottle made of HDPE is acceptable (berglinots are more flexible and can be considered as a worst case). The pH remains also higher than 11 after storage, which is important to stabilize the active ingredient. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: The active substance is protected from light thanks to an opaque PVC packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure . |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | CIPAC MT 47.2 | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | No foam is observed after 1 min at the concentration 5% w/v. | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | The formulation is not a foaming product.  However the product tested is not representative of the whole meta SPC since other products have slight differences in term of composition. Other products are more similar to JAVEL 2.6 CITRON PRO OXENA from meta SPC 3. This product forms significant foam (ie. >60mL after 1 min).  Note: proposed use rates for meta SPC 6 are 0.5-4.4 v/v and are covered by the test at 7% w/v (ie 6.7% v/v) for JAVEL 2.6 CITRON PRO OXENA. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. The mentions EUH031 “contact with acids liberates toxic gas” and EUH 206: Warning! Do not use together with other products. May release dangerous gases (chlorine) should be added for this Meta SPC.  Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | CIPAC MT 179 | **Javel 4.8** 4.8% of active chlorine  Batch 24247 24248 | At 5% m/v concentration, after 18h, presence of supernatant and deposit is observed at the bottom of the flask.  Applicant: Nevertheless, no blockage of the application equipment or unacceptable risk is expected since the formulation is not intented to be applied by spraying. | Y | Peysson, W. (2019)  Report RRCo-000330\_01 | Acceptable as spraying is not claimed for this meta SPC. |
| Surface tension | - | **-** | Not determined | - |  | Surface tension was not provided. However, based on the compositions and read across with product JAVEL 2.6 CITRON PRO/GP (meta SPC 3), products containing surfactants are expected to be surface active.  Only product JAVEL 4.8 GP OXENA is not expected to be surface active due to its composition and cross reading with JAVEL 12.5 PRO OXENA from meta SPC 2. |
| Viscosity | - | **-** | Not determined | - |  | Viscosity has not been provided.  However, based on the compositions and read across with products JAVEL 2.6 CITRON PRO/GP (meta SPC 3) and JAVEL 12.5 PRO OXENA (meta SPC2), products of this meta SPC are expected to be newtonian fluids. |

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| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 6** |
| The formulation **Javel 4.8** is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of **JAVEL 4.8** is that of transparent yellow liquid.  The stability of Javel 4.8 was not demonstrated after storage 2 weeks at 54°C, the active chlorine content decreased strongly (-43.3%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation JAVEL 4.8 was not fully demonstrated after storage 12 months at ambient temperature, the active chlorine content does not decrease significantly but the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. Refer to human health section regarding conclusion on chlorate content.  Five products are claimed for this meta SPC. Compositions are similar and the only relevant change is related to the perfumes/surfactants. Technical properties obtained for the tested product will cover the SPC. However, shelf life for the whole meta SPC cannot be set using results obtained for Javel 4.8 as perfumes/surfactants may influence the degradation rate of active chlorine. Only a shelf life of 12 months can be granted for JAVEL 4.8 GP OXENA (without surfactant/perfume). No shelf life can be proposed for the other products.  Compatibility of the products with HDPE and PVC berlingot/bottle is acceptable.  The formulation JAVEL 4.8 is not a foaming product. However this product is not representative of the whole meta SPC regarding this endpoint (foam) as other products have slight differences in term of composition. Other products are more similar to JAVEL 2.6 CITRON PRO OXENA from meta SPC 3. This product forms significant foam (ie. >60mL after 1 min). However, as only a shelf life can be set for JAVEL 4.8 GP OXENA, no mention “Foaming product” will be proposed.  **Implication concerning labelling for the products of meta SPC 6:**  Shelf life: 12 months (JAVEL 4.8% without perfume)  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia.  EUH031 “contact with acids liberates toxic gas”  EUH 206: Warning! Do not use together with other products. May release dangerous gases (chlorine) |

**META SPC 7 – THICK BLEACH PROFESSIONAL**

Formulation supported in the Meta SPC 7 is GEL JAVEL PRO OXENA, the formulation is a Soluble Concentrate (SL). Assessment of physical, chemical and technical properties of the formulation Javel 4.8 is presented below.

**Gel Javel Pro Oxena**

The biocidal product is a Soluble Concentrate (SL) formulation.

The product does not contain hydrocarbons or H304 co-formulant content ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | **GEL JAVEL PRO OXENA** 2.3%w/w of active chlorine  Batch LAD20181030 | Colourless liquid. | Y | Peysson, W. (2019)  Report RRCo-000389\_01 | Acceptable |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | - | **GEL JAVEL PRO OXENA** 2.3%w/w of active chlorine Batch LAD20181030 | Bitter smell. | Y | Peysson, W. (2019)  Report RRCo-000389\_01 | Acceptable |
| pH of 1% dilution | CIPAC MT 75.3 | **GEL JAVEL PRO OXENA** 2.3% of active chlorine  Batch LAD20181030 | pH of 1% dilution at 19.3°C : 11.3 | Y | Peysson, W. (2019)  Report RRCo-000389\_01 | Acceptable. Neat pH is not available. However diluted pH is 11.3 and product contains NaOH. eCA considers that neat pH is expected to be>11.5. |
| Acidity / alkalinity | CIPAC MT 191 | **GEL JAVEL PRO OXENA** 2.3% of active chlorine  Batch LAD20181030 | Alkalinity: 3.5% as NaOH | Y | Peysson, W. (2019)  Report RRCo-000389\_01 | Acceptable |
| Relative density / bulk density | - | - | Not determined  1.11 (declared by the applicant) | - | - | Acceptable. The proposed density is consistent with the one of the other products of the family. |
| Storage stability test – **accelerated storage** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 46.3  75.3  191  41  47.2 | **GEL JAVEL PRO OXENA** 2.3% of active chlorine  Batch LAD20181030 | |  |  |  | | --- | --- | --- | |  | **Initial** | **2 weeks at 54°C in glass bottle** | | **Active ingredient content** (total active chlorine)  Decrease | 2.42% w/v | 0.87% w/v  (-64%) | | **Sodium chlorate content** | 0.09% w/v | 0.23% w/v | | **Ratio sodium chlorate/av chlorine** | 3.7% w/w | 26.4% w/w | | **Appearance** | Colourless liquid with bitter smell (with deposit after storage) | | | **pH 1% at 20°C** | 11.3 | 11.1 | | **Alcalinity/Acidity** | 3.5 | 2.8 | | **Dilution stability**  **At 7% w/v** | No separated material after 18h | Presence of white foam at the botton of the flask after 18h | | **Persistent foaming at 7% w/v** | 172mL after 1 min | 171mL after 1 min |   Applicant: Significant decrease of the active substance content (-64%) and an increase of sodium chlorate above the acceptable limit of 5.4% of active chlorine content are observed after 2-week storage at 54°C. The formulation is not stable in these conditions. | Y | Peysson, W. (2019)  Report RRCo-000389\_01 | The active ingredient content decreases by more than 10% and the ratio sodium chlorate/av. Chlorine exceeds 5.4% w/w. This increase is due to the unstability of NaOCl at high temperature. Therefore, the product should be stored below 30°C to prevent from faster degradation of the active ingredient. |
| Storage stability test – **long term storage at ambient temperature** | AM1 – ANA MON 102 (chlorine)  AM2 - ANA MON 103  (sodium chlorate)    CIPAC MT 75.3  191  47.2  41 | **GEL JAVEL PRO OXENA** 2.3% of active chlorine  Batch LAD20181030 | The sample was stored at ambient temperature in 1L HDPE bottle   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Initial** | **After 6 months in**  **opaque HDPE** | **After 9 months in opaque HDPE** | **After 1 year in opaque HDPE** | | **Active ingredient content** (total active chlorine)  Decrease | 2.42% w/v | 2.16% w/v  (-10.7%) | 2.13% w/v  (-12%) | 2.03% w/v  (-16.1%) | | **Sodium chlorate content** | 0.09% w/v | 0.13 % w/v | 0.20 % w/v | 0.19% w/v | | **Ratio sodium chlorate/av chlorine** | 3.7% w/w | 6% w/w | 9.4% w/w | 9.4% w/w | | **Appearance** | Product: colourless liquid, slightly yellow, bitter smell odour  Packaging: no crack, no swelling, no change of colour | | | | | **pH 1% at 20°C** | 11.3 | 11.4 | 11.9 | 11.3 | | **Alcalinity/Acidity** | 3.52% | 3.45% | 3.90% | 3.15% | | **Dilution stability**  **At 7% w/v** | No separated material after 18h | | | | | **Persistent foaming at 7% w/v** | 172mL after 1 min | 177mL after 1 min | 156mL after 1min | 110mL after 1 min |   Applicant: No significant change is observed in the active substance content. Variability of the results is due to variability of the method rather than active substance decrease. However the sodium chlorate content is above the acceptable limit of 5.4% of active chlorine content. The sodium chlorate content after 1-year storage is taken into account for the risk assessment for human and environment.  There is no significant change in the physical and chemical properties of the formulation.  Provided those explanations are con-sidered appropriate, a shelf life of 12 months could be provided. | N  (mid term report) | Peysson, W. (2020)  Report RRCo-000390\_01 | The content of active chlorine decreases by more than 10%.  The ratio sodium chlorate/av chlorine exceeds the limit of 5.4% after storage 1 year. Refer to human health section regarding conclusion on chlorate content. However, efficacy was not fully addressed for this meta SPC. Consequently, no shelf life up to 1 year can be set . A shelf life up to 5 months can be proposed (variations of active substance content are expected to be <10% by comparison with results after 6 months).  Other properties and compatibility with HDPE are acceptable. The pH remains also higher than 11 after storage, which is important to stabilize the active ingredient.  Dilution stability and persistent foaming are not necessary since the product is not intended to be diluted. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Applicant: Not needed, mention is made on the label not to store under 0°C. | - | - | Acceptable. The product should be protected from frost. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Applicant: the active substance is protected from light thanks to an opaque HDPE packaging and mention is made on the label “protect from direct sunlight”. | - | - | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. eCA agrees with the applicant on the proposed mitigation measure. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | According to the results of accelerated storage stability study, the product should be kept stored below 30°C to prevent from faster degradation of the active ingredient. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See ”Storage stability test – **long term storage at ambient temperature”** | - | - | See results of long term storage stability study performed with HDPE bottle. |
| Wettability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Wet sieve analysis and dry sieve test | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Disintegration time | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Particle size distribution | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Content of dust/fines | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Attrition, friability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Persistent foaming | - | **-** | Not relevant for a ready-to-use formulation | - | - | Not applicable since the product is ready to use. |
| Flowability/Pourability/Dustability | - | - | Not relevant (liquid formulation) | - | - | Not relevant for SL formulation. |
| Burning rate — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Burning completeness — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Composition of smoke — smoke generators | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Spraying pattern — aerosols | - | - | Not relevant | - | - | Not relevant for SL formulation. |
| Physical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite is a strong oxidant. Metallic packaging should be avoided. As HDPE material is claimed for packaging, no further concern should be raised. |
| Chemical compatibility | - | - | Not relevant (liquid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.  Note that for products with a content of active substance<5% w/w, the mention EUH031 is not necessary.  Products should not be used in conjunction with acids or ammonia. |
| Dilution stability | - | **-** | Not relevant for a ready-to-use formulation | - | - | Not applicable since the product is ready to use. |
| Surface tension | EC A.5. method (2008) and OECD Guideline No. 115 (1995) | CLORIGEL (GEL JAVEL PRO OXENA) 2.3% of active chlorine, batch LAD20181030 | The mean surface tension of the pure test item at 20.1 °C was 31.3 mN/m. The test item was considered as surface-active in the experimental conditions used. | - | - | Acceptable. The product is surface active. |
| Viscosity | OECD Guideline No. 114 (2012) and ISO Standard 3219 (1993) | CLORIGEL (GEL JAVEL PRO OXENA) 2.3% of active chlorine, batch LAD20181030 | Taking into account the results obtained at 20.0 °C and 40.0 °C, the test item was considered to have newtonian properties in the experimental conditions used. The mean dynamic viscosity of the test item was 23.0 mPa.s at 20.0 °C ± 0.2 °C and 17.8 mPa.s at 40.0 °C ± 0.2 °C | - | - | Acceptable. |

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| **Conclusion on the physical, chemical and technical properties of the products supported in Meta-SPC 7** |
| The formulation **GEL JAVEL PRO OXENA** is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements of the Biocidal Products Regulation. The appearance of **GEL JAVEL PRO OXENA** is that of transparent colorless liquid.  The stability of GEL JAVEL PRO OXENA was not demonstrated after storage 2 weeks at 54°C, the active chlorine content decreased strongly (-64%) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. However, a mitigation measure is proposed by applicant: do not store above 30°C.  The stability of the formulation GEL JAVEL PRO OXENA was not fully demonstrated after storage 12 months at ambient temperature, the active chlorine content decreases significantly (>10% of initial content) and the sodium chlorate content was found above the maximum limit of 5.4% of the active chlorine content. Refer to human health section regarding conclusion on chlorate content. However, efficacy was not fully addressed for this meta SPC and no shelf life up to 12 months can be set. Using available data, a shelf life up to 5 months can be proposed since variations regarding active substance content are below 10%.  Compatibility of the product with HDPE is acceptable.  **Implication concerning labelling for the product of meta SPC 7:**  Shelf life: 5 months  Protect from frost.  Protect from direct sunlight.  Do not store above 30°C.  Products should not be used in conjunction with acids or ammonia. |

### Physical hazards and respective characteristics

No studies have been provided by the applicant.

Due to the similarity between formulations of the biocidal product family, a common table has been prepared since scientific cases/waivers are mainly proposed.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **GLP** | **Reference** | **eCA assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaOCl (16.7%) are not explosive. Additionally, other compounds do not possess chemical functions related to explosive properties and the products are aqueous solution with a high proportion of water. Therefore, products of the family are not classified. |
| Flammable gases |  |  | Not relevant |  |  | Not relevant |
| Flammable aerosols |  |  | Not relevant |  |  | Not relevant. |
| Oxidising gases |  |  | Not relevant |  |  | Not relevant. |
| Gases under pressure |  |  | Not relevant |  |  | Not relevant. |
| Flammable liquids |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | The products is a mineral aqueous solution which contain less than 8% of organic compounds and none of them except perfumes (max 0.04% w/w) are considered flammables ( brief profile and C&L inventory from ECHA). eCA considers that products are not classified as flammable according to CLP and Reach regulation 1907/2006. |
| Flammable solids |  |  | Not relevant |  |  | Not relevant. |
| Self-reactive substances and mixtures |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | Not relevant since no compound is classified explosive or self reactive. Additionally, sodium hypochlorite does not decompose strongly exothermically.  According to Guidance on the application of the CLP criteria, “*substances and mixtures must be considered for classification in this hazard class unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria”*.  For Meta SPCs containing only active substance and water, a waiving is acceptable. All other Meta SPCs may contain formulants as complexing agents, surfactants, perfumes and they do not satisfy the waiver for chemical group associated with self reactive properties. However, in view of very low concentrations of compounds and the absence of explosive properties, eCa is of opinion that requesting a full test is not appropriate. eCA rather proposes to request a DSC test in post registration to confirm the non classification in this hazard class for those meta-SPCs. |
| Pyrophoric liquids |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | Not relevant. |
| Pyrophoric solids |  |  | Not relevant |  |  | Not relevant. |
| Self-heating substances and mixtures |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | Not relevant due to the composition of the family product. Not applicable to products with a melting point below 160°C. |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | In water, sodium hypochlorite can be converted in chlorine gas. However, this is relevant at low pH (<4). In this case, the pH of the product is kept >11 due to stability of the active substance. Additionally, chlorine is not known to be a flammable gas. No further data are deemed necessary. |
| Oxidising liquids |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaOCl (25.3%) are not considered as oxidizing liquid.  According to ECHA guidance on the application of CLP criteria, no classification is necessary if compounds present oxygen atom only bonded to carbon or hydrogen. For some formulant, oxygen can be bonded to other atoms than carbon and hydrogen. A test would be relevant for Meta SPC 1,3,4,5,6,7. Meta SPC 2 is covered with tested products from the CAR. FR considers that based on the current classification of individual ingredients, no specific concern is expected.  Furthermore, according to ECHA guidance of the CLP criteria, the following consideration should be taken into account for oxidizing liquids:  “**In case a mixture of an oxidising substance and a non-hazardous inert substance is offered for classification, the following should be taken into account**:  1/An inert material by definition does not contribute to the oxidising capability of the oxidising substance. Hence, the mixture can never be classified into a more severe hazard category.  2/If an oxidising substance is mixed with an inert material, the oxidising capability of the mixture does not linearly decrease with decreasing content of oxidising substance. The relationship is more or less logarithmic and depends on the characteristics of the oxidising substance. For instance, a mixture containing 50 % of a strong oxidiser and 50 % of an inert material may retain 90 % of the oxidising capability of the original oxidising component. Non-testing classification of mixtures based solely on test data for the original oxidising substance should therefore be done with extreme care and only, if sufficient experience in testing exists.  **3/The determination of the oxidising properties of an aqueous solution of solid oxidising substances and the classification as an oxidising mixture is not necessary provided that the total concentration of all solid oxidisers in the aqueous solution is less than or equal to 20 % (w/w)**.”  According to this guidance, we understand that if an oxidising substance is mixed with water at a content up to 20% w/w, there is no need to classify this mixture. In this dossier, the content of water in each product is always >80%, and the remaining organic coumpounds represent less than 10% w/w. If they were considered as oxidizing substances (worst case), the classification would not be necessary as their content is below 20% w/w.  Therefore, FR consider that further testing would not be necessary with these explanations. Products do not possess oxidizing properties. |
| Oxidising solids |  |  | Not relevant |  |  | Not relevant |
| Organic peroxides |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | Not relevant |
| Corrosive to metals | UN Test C.1 | **Javel 4.8** 4.8%w/w of active chlorine Batch 24064 | The Assessment Report of active chlorine released from sodium hypochlorite states “common metals should never be used for the storage or handling of sodium hypochlorite solution”. Both products are expected to be corrosive to metals and thus are classified Met. Corr. 1.  **SPC 1:** Met. Corr. 1  **SPC 2:** Met. Corr. 1  **SPC 5:** Met. Corr. 1 | Y | Zampieri, L. (2018)  Report N° 18.647013.0001 | Products from meta SPC 1, 2 and 5 are classified Met. Corr. 1 by read across with other products tested for this hazard. This classification is consistent since a test provided for product JAVEL 4.8% GP OXENA (meta SPC 6) was submitted and it was demonstrated that this product is classified. Since products of meta SPC 1, 2 and 5 contains higher amount of av. Chlorine and new formulants, it can be considered that JAVEL 4.8% GP OXENA is a worst case. Consequently, products of meta SPC 1, 2 and 5 are classified **Met. Corr. 1.** |
| Corrosive to metals (meta SPC3, SPC4 and SPC 7) | UN Test C.1 | **Javel 2.6** 2.6 %w/w of active chlorine  Batch 18002195 | For the Steel specimens a significant corrosion phenomena (mass loss more than 13.5% for an exposure time of 7 days) is observed for dipped and half-dipped plates (respectively 22.7% and 17.9% of mass loss). For the Aluminum plates a significant corrosion phenomena (mass loss more than 13.5% for an exposure time of 7 days) is observed for dipped plates (15.4% of mass loss). No corrosion phenomena occurred for the steel specimen exposed to the sample gas phase and for aluminium plates half-dipped and exposed to the sample gas phase (mass loss less than 13.5% for an exposure time of 7 days).  Accordig to the UN Test C.1 classification criteria, the test is considered positive. | Y | Zampieri, L. (2019)  Report N° 18.652005.0001 | The formulation is classified as corrosive to metals: **Met. Corr. 1.**  Products belonging to meta SPC 3 and 4 are classified.  As product of meta SPC 7 has a close composition and contains other compounds which are corrosive to metals, results obtained for JAVEL 2.6 PRO/GP OXENA can be extrapolated to GEL JAVEL PRO OXENA. |
| Corrosive to metals (meta SPC 3, SPC 4 and SPC 7) | UN Test C.1 | **Javel 2.6** 2.6 %w/w of active chlorine  Batch 19M000218 | For the Steel specimens a significant corrosion phenomena (mass loss more than 13.5% for an exposure time of 7 days) is observed for dipped and half-dipped plates (respectively 19.1% and 11.1% of mass loss). No corrosion phenomena occurred for the steel specimen exposed to the sample gas phase (mass loss less than 13.5% for an exposure time of 7 days).  For the entire set of Aluminium plates no corrosion phenomena occurred (mass loss in all the cases less than 13.5% for an exposure time of 7 days).  Accordig to the UN Test C.1 classification criteria, the test is considered positive. | Y | Zampieri, L. (2019)  Report N° 19.505711.0001 | The formulation is classified as corrosive to metals: **Met. Corr. 1**  Products belonging to meta SPC 3 and 4 are classified.  As product of meta SPC 7 has a close composition and contains other compounds which are corrosive to metals, results obtained for JAVEL 2.6 PRO/GP OXENA can be extrapolated to GEL JAVEL PRO OXENA. |
| Corrosive to metals (meta SPC 6) | UN Test C.1 | **Javel 4.8** 4.8%w/w of active chlorine Batch 24064 | For the Steel specimens a significant corrosion phenomena (mass loss more than 13.5% for an exposure time of 7 days) is observed for dipped and half-dipped plates (respectively 18.6% and 24.9% of mass loss). No corrosion phenomena occurred for the steel specimen exposed to the sample gas phase (mass loss less than 13.5% for an exposure time of 7 days).  For the entire set of Aluminium specimen no corrosion phenomena occurred (mass loss in all the cases less than 13.5% for an exposure time of 7 days).  Accordig to the UN Test C.1 classification criteria, the test is considered positive. | Y | Zampieri, L. (2018)  Report N° 18.647013.0001 | The formulation is classified as corrosive to metals: **Met. Corr. 1.**  Products belonging to meta SPC 6 are classified. |
| Auto-ignition temperatures of products (liquids and gases) |  |  | Waived on the basis of the classification (The product does not contain any component classified regarding this physical hazard, it is thus not classified for this physical hazard). |  |  | In the CAR, it has been concluded that sodium hypochlorite is not auto-flammable. Additionally, as produts are aqueous solution with a high proportion of water, no specific concern is raised and products are not considered as auto flammable. |
| Relative self-ignition temperature for solids |  |  | Not relevant |  |  | Not relevant. |
| Dust explosion hazard |  |  | Not relevant |  |  | Not relevant. |

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| **Conclusion on the physical hazards and respective characteristics of the biocidal product family** |
| Products are not explosive, flammable or auto-flammable and do not possess oxidizing properties. All products of the family are classified Met. Corr. 1. The products are not classified regarding other physical hazards. **A DSC test and a study for oxidizing property on representative products of the BPF should be provided in post registration in order to confirm that products are not self reactive.**  **Classification for all meta SPCs: H290 Met Corr. 1, GHS05, Danger** |

### Methods for detection and identification

**Analytical Method 1: determination of active chlorine in the products (AM1)**

Active chlorine content is measured with spectrophotometer by external calibration. At neutral pH, active chlorine reacts with DPD and forms a coloured complex. Just after preparation in measuring cell, solutions were shaken during 10 seconds and absorbance at 550 nm was read quickly after preparation. The auto zero was performed with the blank.

Based of % active chlorine and co-formulants 3 groups were formed:

* Group 1 at 12.5 % active chlorine : representative of Javel 12.5 %
* Group 2 at 5.5 % active chlorine : representative of Alca 6.3 %, Decap ACM 5% and Javel 4.8 %
* Group 3 at 2.6% active chlorine : representative of Javel 2.6 %, Javel 2.6 % citron and Javel 2.6 % detergente citron

Assessment of the bridging and identity on the tested formulation and validation data are reported in confidential annex due to confidential business information.

**Analytical Method 2: determination of sodium chlorate in the products (AM2)**

Chlorate were measured by ion chromatography by external calibration and expressed as sodium chlorate by the following equation: 𝐶Na(ClO3)= 𝐶ClO3− 𝑥 𝑀Na(ClO3) /𝑀ClO3−. This method is similar to method ISO 10304-4 for the determination of chlorates in water.

Validation was performed using formulations of group 1, group 2 and group 3. Assessment of the bridging and identity on the tested formulation and validation data are reported in confidential annex due to confidential business information.

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| **Conclusion on the methods for detection and identification of the product** |
| An analytical method for the determination of active chlorine in the products has been provided and is considered as validated.  An analytical method for the determination of the relevant impurity, sodium chlorate, in the products has been provided and is considered as validated. **However a validation at a lower LOQ should be provided in order to comply with the limit set at EU level. Data are required in post registration.** |

**Analytical methods for monitoring**

Analytical methods for determination of the active substance residues in various matrices have been provided at EU level and assessed in the Assessment Report of Active chlorine released from sodium hypochlorite (January 2017 and confirmatory data 2018). Analytical methods are brielfly summarised below. OXENA has access to this data thanks to a Letter of Access.

Analytical methods for soil

No method is required as Active chlorine (HClO/ClO─) reacts rapidly with organic matter.

Analytical methods for air

No method is required, nevertheless, two analytical methods were provided and validated at EU level for the determination of chlorine in workplace air.

Analytical methods for water

Drinking water: analytical methods for determination of the active chlorine (HClO/ClO─) and the relevant metabolite chlorate (ClO3─) in drinking water were reviewed at EU level.

Surface water: No method is required as Active chlorine (HClO/ClO─)reacts rapidly with organic matter.

Analytical methods for animal and human body fluids and tissues

No method is required as Active chlorine (HClO/ClO─) reacts rapidly with organic matter.

Analytical methods for monitoring of active substances and residues in food and feeding stuff

No method required for Active chlorine (HClO/ClO─) as it reacts rapidly in contact with food/feed matrices. Analytical methods for determination of the relevant metabolite chlorate (ClO3─) in food/feed of animal origin were reviewed at EU level.

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| **Conclusion on the methods for detection and identification of residues of active substance for monitoring** |
| For soil, air, surface water, body fluids and tissues, the applicant has access to the CAR of the active substance. According to the Assessment Report of Active chlorine released from sodium hypochlorite (January 2017), considering the reactivity of active chlorine with organic matter, no method is required for the determination of the active chlorine (HClO/ClO─) in soil, surface water and animal and human body fluids and tissues.  Fully validated methods for the determination of active chlorine in water and relevant impurity chlorate in drinking water, food and animal products have also been provided in the CAR of the active substance (confirmatory data assessed and peer reviewed by eCA IT in 2018) |

### Efficacy against target organisms

#### **Function and field of use**

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals.

PT4: Food and feed area.

The biocidal product family based on the active substance active chlorine released from sodium hypochlorite, consists of 7 META-SPC and is intended for use in Product Type (PT) 2 and 4 for the following applications:

Product Type 2:

* #1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) (Non medical sector and Medical sector) by pouring, without mechanical action, for META-SPC 2, META-SPC 3, META-SPC 4, META-SPC 6, META-SPC 7;
* #2 - Disinfection of hard surfaces, use other than in healthcare by spraying, wiping, pouring, mopping or scrubbing, with mechanical action, for META-SPC2, META-SPC3, META-SPC4, META-SPC6, META-SPC7;
* #3 - Disinfection of hard surfaces, use in healthcare, spraying, wiping, pouring, mopping or scrubbing, with mechanical action, for META-SPC 2, META-SPC 3;
* #4 - Anti-lichen and anti-algae treatment of hard surfaces (such as wall, floor, roof, etc.) by spraying (Non medical sector, outdoor), without mechanical action, for META-SPC 5;
* #6 – Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) (Non medical sector and Medical sector), for META-SPC 1, META-SPC 2, META-SPC 3;
* #7 - Disinfection of equipment/materials by immersion/dipping/soaking, without mechanical action, (Non medical sector), for META-SPC2, META-SPC 3.

Product Type 4:

* #5 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing, with mechanical action, for META-SPC 1, META-SPC 2, META-SPC 3, META-SPC 4, META-SPC 6, META-SPC 7;
* #6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels), for META-SPC1, Meta-SPC 2, META-SPC 3;
* #7 - Disinfection of equipment/materials by immersion/dipping/soaking, without mechanical action, for META-SPC 2, META-SPC 3;
* #8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP) by pouring, for META-SPC 1, META-SPC 2, META-SPC 3;
* #9 - Disinfection of surfaces of inner surfaces in veterinary water systems by pouring, without mechanical action, for META-SPC 1, META-SPC 2.

The products are used by industrial, professional and non-professional users.

#### **Organisms to be controlled and products, organisms or objects to be protected**

The biocidal products are intended to be usedto control bacteria, yeasts, fungal spores, viruses, algae and lichens.

The product family is used for the purpose of the protection of human and animal health.

#### **Effects on target organisms, including unacceptable suffering**

The products are able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), of fungal spores (fungicidal activity), algae and lichen cells (algicidal and anti-lichen activity) and of infectious virus particles (virucidal activity) of relevant test organisms under defined conditions.

#### **Mode of action, including time delay**

According to the Assessment Report of the active substance, the hypochlorite ion is in equilibrium with hypochlorous acid (HOCl) and chlorine (sum: active chlorine or available chlorine) depending on the pH value: below pH 4 chlorine is available, in the neutral pH range hypochlorous acid is the predominant species and at pH values higher then 10, the only species present is the hypochlorite ion.

Hypochlorite reacts actively by chlorination of nitrogen with compounds like amino acids. The disinfecting efficiency of hypochlorite aqueous solution is dependent on the active chlorine concentration and decreases with an increase in pH. It is irrelevant whether available chlorine is generated from chlorine gas, calcium hypochlorite or sodium hypochlorite.

Contact times for the different activities claimed are determined in the efficacy tests (see tables below).

#### **Efficacy data**

* **Tested products:**

The biocidal product family OXENA FAMILY consists of products containing the active substance Sodium Hypochlorite in the range of 2.2 to 12.5 % w/w active chlorine.

Laboratory studies were conducted with different reference formulations in accordance with the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C).

The results are summarized in Section 6.7 of the IUCLID file and the main efficacy data are summarized in the table below.

According to the Guidance on the BPR Vol.II part B/C,

* for PT2:
* For disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring in non-medical sector (# 1) and for disinfection of hard surfaces other than in healthcare by spraying, wiping, pouring, mopping or scrubbing (# 2): phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; yeasts, fungal spores and viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of hard surfaces in healthcare by spraying, wiping, pouring, mopping or scrubbing (# 3): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores, viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of equipment/materials by automatic spraying in closed systems (tunnels) (#6), eCA considered it equivalent to “Disinfection in dishwashing machines and crate washers”. For this use, for all test organisms phase 2 step 1 tests, phase 2 step 2 tests and phase 3 tests are required.
* For disinfection of non medical equipment/materials by immersion/soaking (# 7): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed (except for viruses).
* For disinfection of inner surfaces without circulation, requirements are the same as for hard surfaces.
* for PT4:
* For disinfection of hard surfaces (#5): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.
* For disinfection of equipment/materials by automatic spraying in closed systems (tunnels) (#6), eCA considered it equivalent to “Disinfection in dishwashing machines and crate washers”. For this use, for all test organisms phase 2 step 1 tests, phase 2 step 2 tests and phase 3 tests are required.
* For disinfection of equipment/materials by immersion/soaking (# 7): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 (fungal spores only) tests are needed.
* For disinfection of inner surfaces by CIP (#8): phase 2 step 1 tests on bacteria and yeasts are basic requirements; fungal spores and viruses are optional organisms for which phase 2 step 1 tests are also needed. For disinfection of inner surfaces without circulation, requirements are the same as for hard surfaces.
* For disinfection of inner surfaces in veterinary water systems (# 9): phase 2 step 1 and phase 2 step 2 tests on bacteria are basic requirements; yeasts, fungal spores, and viruses are optional organisms for which phase 2 step 1 and phase 2 step 2 tests are needed.

**Summary of efficacy studies performed on the biocidal products included in the Biocidal Product Family.**

The table summarised all the efficacy studies performed on the biocidal products, and the minimum concentration necessary to achieve the desired effect (i.e. bactericidal, fungicidal, yeasticidal and virucidal activities) for each biocidal products tested in both clean and dirty conditions.

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 1, 2, 3, 4 and 7, clean conditions.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Meta-SPC 1** | | | | **Meta-SPC 2** | | | **Meta-SPC 3 and 4** | | | | | | | | | **Meta-SPC 7** |
|  |  | **PT 4** | | | | **PT 2,4** | | | **PT 2,4** | | | | | | | | | **PT 2,4** |
| **Test method/ Product Name** | | **OXE ALCA** | **OXE ALCA (T +6mois)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T +6mois)** | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6mois)** | **Javel 9,6 PRO OXENA** | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA (T +12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** | **Gel Javel PRO** |
| **Soiling conditions: Clean** | | **Minimum effective dose of active chlorine (expressed as % of product)** | | | | | | | | | | | | | | | | |
| EN 13697 - 5 min (2,2) | Bactericide | 0.3 | 0.5 | 0.3 | 0.5 | 0.4 | 0.4 | 0.5 |  | 1.5 | 2 |  | 1.5 |  |  |  | 1.5 |  |
| EN 13697 - 15 min (2,2) | Fungicide | 2 | 3 | 2 | 3 | 0.8 | 1.5 | 0.8 |  | 4 | 5 |  | 3 |  |  |  | 4 |  |
| Yeasticide | 0.3 | 0.5 | 0.3 | 1% | 0.2 | 1 | 0.5 |  | 1 | 1 |  | 1 |  |  |  | 1 |  |
| NF EN 1276 (2,1) | Bactericide | 0.3 | 0.7 | 0.2 | 0.5 | 0.2 | 0.3 | 0.2 |  | 0.8 | 0.8 |  | 0.5 |  |  |  | 0.5 |  |
| NF EN 1650 (2,1) | Fungicide | 1 | 1.5 | 1 | 1.5 | 0.6 | 1.5 | 0.8 |  | 2 | 2 |  | 2 |  |  |  | 2 |  |
| Yeasticide | 0.3 | 0.3 | 0.2 | 0.5 | 0.1 | 0.5 | 0.1 |  | 0.8 | 0.8 |  | 0.5 |  |  |  | 0.8 |  |
| EN 13624 (2,1) | Fungicide |  |  |  |  |  |  |  |  |  |  |  | 2.31 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 0.31 |  |  |  |  |  |
| EN 13727 - 15 min (2,1) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 0.15 |  |  |  |  |  |
| EN14476 - 15 min (2,1) | Virucide |  |  |  |  |  |  |  |  |  |  |  | n/t |  |  |  |  |  |
| EN 16615 - 5 min (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 1.54 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 1.54 |  |  |  |  |  |
| EN 16615 - 15 min (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 0.31 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 0.31 |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Meta-SPC 1** | | | | **Meta-SPC 2** | | | **Meta-SPC 3 and 4** | | | | | | | | | **Meta-SPC 7** |
|  |  | **PT 4** | | | | **PT 2,4** | | | **PT 2,4** | | | | | | | | | **PT 2,4** |
| **Test method/ Product Name** | | **OXE ALCA** | **OXE ALCA (T +6mois)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T +6mois)** | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6mois)** | **Javel 9,6 PRO OXENA** | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron  PRO OXENA** | **Javel 2,6 detergence citron  PRO OXENA (T +12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** | **Gel Javel PRO** |
| **Soiling conditions: Clean** | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | | | | | | | | | | | | | | | |
| EN 13697 - 5 min (2,2) | Bactericide | 197 | 284 | 172 | 218 | 562 | 315 | 552 |  | 402 | 433 |  | 402 |  |  |  | 403 |  |
| EN 13697 - 15 min (2,2) | Fungicide | 1316 | 1701 | 1145 | 1305 | 1123 | 1180 | 883 |  | 1071 | 1082 |  | 803 |  |  |  | 1075 |  |
| Yeasticide | 197 | 284 | 172 | 435 | 281 | 787 | 552 |  | 268 | 216 |  | 268 |  |  |  | 269 |  |
| NF EN 1276 (2,1) | Bactericide | 204 | 397 | 115 | 218 | 286 | 236 | 221 |  | 219 | 177 |  | 134 |  |  |  | 134 |  |
| NF EN 1650 (2,1) | Fungicide | 658 | 851 | 573 | 653 | 857 | 1180 | 883 |  | 536 | 433 |  | 536 |  |  |  | 537 |  |
| Yeasticide | 197 | 170 | 115 | 218 | 143 | 394 | 110 |  | 219 | 177 |  | 134 |  |  |  | 215 |  |
| EN 13624 (2,1) | Fungicide |  |  |  |  |  |  |  |  |  |  |  | 618 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 82 |  |  |  |  |  |
| EN 13727 (2,1) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 41 |  |  |  |  |  |
| EN 14476 - 15 min (2,1) | Virucide |  |  |  |  |  |  |  |  |  |  |  | n/t |  |  |  |  |  |
| EN 16615 - 5 min (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 412 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 412 |  |  |  |  |  |
| EN 16615 - 15 min (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 82 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 82 |  |  |  |  |  |

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 1, 2, 3, 4 and 7, dirty conditions.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Meta-SPC 1** | | | | **Meta-SPC 2** | | | **Meta-SPC 3 and 4** | | | | | | | | | **Meta-SPC 7** |
|  |  | **PT 4** | | | | **PT 2,4** | | | **PT 2,4** | | | | | | | | | **PT 2,4** |
| **Test method/ Product Name** | | **OXE ALCA** | **OXE ALCA (T +6mois)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T +6mois)** | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6mois)** | **Javel 9,6 PRO OXENA** | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA (T +12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** | **Gel javel PRO** |
| **Soiling conditions: Dirty** | | **Minimum effective dose of active chlorine (expressed as % of product)** | | | | | | | | | | | | | | | | |
| NF EN 13697 - 5 min - 3 g/L BSA (2,2) | Bactericide | 1.5 | 6 | 3 | 4 | 1.5 | 3 | 1.5 |  | 1.5 | 8 |  | 7 |  |  |  | 7 | Not valid |
| NF EN 13697 - 15 min - 3 g/L BSA (2,2) | Fungicide | 3 | 5 | 3 | 3 | 2 | 4 | 2 |  | 4 | 9 |  | 8 |  |  |  | 8 | 7 |
| Yeasticide | 1 | 1.5 | 1.5 | 3 | 1 | 1.5 | 1 |  | 1 | 4 |  | 3 |  |  |  | 4 | n/t |
| NF EN 1276 (2,1) | Bactericide | 1 | 1.5 | 1 | 2 | 0.8 | 1 | 0.8 |  | 3 | 4 |  | 4 |  |  |  | 3 | Not valid |
| NF EN 1650 (2,1) | Fungicide | 1.5 | 2.5 | 2 | 2.5 | 1.5 | 3 | 1.9 |  | 6 | 8 |  | 7 |  |  |  | 6 | Not valid |
| Yeasticide | 1 | 1.5 | 1 | 2 | 0.7 | 1 | 0.8 |  | 3 | 3 |  | 3 |  |  |  | 3 | n/t |
| EN 13624 - 5 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Fungicide |  |  |  |  |  |  |  |  |  |  |  | 17.7 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 7.7 |  |  |  |  |  |
| EN 13624 – 15 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Fungicide |  |  |  |  |  |  |  |  |  |  |  | 4.62 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 0.39 |  |  |  |  |  |
| EN 13727 - 5 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 6 |  |  |  |  |  |
| EN 13727 - 15 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 0.31 |  |  |  |  |  |
| EN14476 (2,1) - 5 min - 3 g/L BSA + 3 ml/L erythrocytes | Virucide |  |  |  |  |  |  |  |  |  |  |  | 12 |  |  |  |  |  |
| EN14476 (2,1) - 15 min - 3 g/L BSA + 3 ml/L erythrocytes | Virucide |  |  |  |  |  |  |  |  |  |  |  | 7.7 |  |  |  |  |  |
| EN 16615 - 5min - 3 g/L BSA+3 ml/L erythrocytes (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 2.3 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 2.3 |  |  |  |  |  |
| EN 16615 - 15 min - - 3 g/L BSA+3 ml/L erythrocytes (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 0.31 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 0.39 |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Meta-SPC 1** | | | | **Meta-SPC 2** | | | **Meta-SPC 3 and 4** | | | | | | | | | **Meta-SPC 7** |
|  |  | **PT 4** | | | | **PT 2,4** | | | **PT 2,4** | | | | | | | | | **PT 2,4** |
| **Test method/ Product Name** | | **OXE ALCA** | **OXE ALCA (T +6mois)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T+6mois)** | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T+6mois)** | **Javel 9,6 PRO OXENA** | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA (T+12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** | **Gel Javel PRO** |
| **Soiling conditions: Dirty** | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | | | | | | | | | | | | | | | |
| NF EN 13697 - 5 min (2,2) | Bactericide | 987 | 3402 | 1718 | 1741 | 2106 | 2361 | 1656 |  | 402 | 1730 |  | 1875 |  |  |  | 1808 | Not valid |
| NF EN 13697 - 15 min (2,2) | Fungicide | 1973 | 2836 | 1718 | 1305 | 2809 | 3148 | 2208 |  | 1071 | 1947 |  | 2142 |  |  |  | 2067 | 1771 |
| Yeasticide | 658 | 851 | 859 | 1305 | 1404 | 1180 | 1104 |  | 268 | 865 |  | 803 |  |  |  | 1033 | n/t |
| NF EN 1276 (2,1) | Bactericide | 681 | 851 | 573 | 870 | 1143 | 787 | 883 |  | 803 | 865 |  | 1071 |  |  |  | 806 | Not valid |
| NF EN 1650 (2,1) | Fungicide | 987 | 1418 | 1145 | 1088 | 2143 | 2361 | 2098 |  | 1607 | 1730 |  | 1875 |  |  |  | 1612 | Not valid |
| Yeasticide | 658 | 851 | 573 | 870 | 1000 | 787 | 883 |  | 803 | 649 |  | 803 |  |  |  | 806 | n/t |
| EN 13624 - 5 min (2,1) | Fungicide |  |  |  |  |  |  |  |  |  |  |  | 4738 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 2060 |  |  |  |  |  |
| EN 13624 - 15 min (2,1) | Fungicide |  |  |  |  |  |  |  |  |  |  |  | 1236 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 103 |  |  |  |  |  |
| EN 13727 - 5 min (2,1) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 1607 |  |  |  |  |  |
| EN 13727 - 15 min (2,1) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 82 |  |  |  |  |  |
| EN14476 (2,1) - 5 min | Virucide |  |  |  |  |  |  |  |  |  |  |  | 3214 |  |  |  |  |  |
| EN14476 (2,1) - 15 min | Virucide |  |  |  |  |  |  |  |  |  |  |  | 2060 |  |  |  |  |  |
| EN 16615 - 5min (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 618 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 618 |  |  |  |  |  |
| EN 16615 - 15 min (2,2) | Bactericide |  |  |  |  |  |  |  |  |  |  |  | 82 |  |  |  |  |  |
| Yeasticide |  |  |  |  |  |  |  |  |  |  |  | 103 |  |  |  |  |  |

**1) Meta-SPC 1 – Food industry:**

#5 PT4-disinfection of hard surfaces (with mechanical action)

#6 PT4-disinfection of equipment/materials in closed systems (tunnels)

#8 PT4-disinfection of inner surface by CIP

#9 PT4-disinfection of surfaces in veterinary water systems (without mechanical action)

META-SPC1 contains products to be diluted containing active chlorine between 5 and 6.3 % w/w, and variations of coformulants, notably surfactants.

Efficacy studies were performed with 2 formulations, OXE ALCA (6,3 % w/w active chlorine, without surfactant) and OXE ALCA CHLORE MOUSSANT (5% w/w active chlorine with surfactant), in order to evaluate the effect of different parameters such as active substance concentration, coformulant related to detergent function and atypical composition.

Phase 2 step 1 and phase 2 step 2 tests were performed with bacteria, yeasts and fungal spores (EN 1276, EN 1650 and EN 13697, 20°C, 5 and 15 min contact times, clean and dirty conditions).

Moreover, as significant decrease of the active substance is observed, for both OXE ALCA and OXE ALCA CHLORE MOUSSANT, during long-term storage stability study (-18 % after 5 months, corresponding to 5.5% m/v and 4.0% m/v of active chlorine respectively), efficacy tests were also performed on 6-month aged formulations. Indeed, according to the Technical Agreements for Biocides (TAB, point 12), if the active substance concentration decreases with more than 10 % during the claimed shelf-life, test can be performed with the claimed organism most difficult to kill (based on the fresh product data) with aged product that has been stored for the complete claimed shelf life to support the efficacy for the claimed shelf-life. Then, in order to demonstrate the bactericidal activity of aged products, tests have been submitted only on *Enterococcus hirae.* Based on data on the fresh products, except for one test (EN1276 in clean conditions), *E.hirae* has been demonstrated to be the bacterium the most difficult to kill. As for the fresh product the tests according to EN1276 in dirty conditions (fresh and aged product) and EN 13697 in clean and dirty conditions demonstrated that *E.hirae* is the most difficult to kill, the EN1276 in clean conditions performed on *E.hirae* with the aged product has been considered acceptable.

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 1, clean conditions

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Test method/ Product Name** | | **OXE ALCA** | **OXE ALCA (T+6 month)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T+6 month)** | **OXE ALCA** | **OXE ALCA (T+6 month)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T+6 month)** |
|  | | **Minimum effective dose expressed as % of product** | | | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | | |
| **Soiling conditions: Clean** | |  | | | |  | | | |
| EN 13697 - 5 min – 0.3 g/L BSA (2,2) | Bactericide | 0.3 | 0.5  (*E.hirae*) | 0.3 | 0.5 (*E.hirae*) | 197 | 284 (*E.hirae*) | 172 | 218 (*E.hirae*) |
| EN 13697 - 15 min – 0.3 g/L BSA (2,2) | Fungicide | 2 | 3 | 2 | 3 | 1316 | 1701 | 1145 | 1305 |
| Yeasticide | 0.3 | 0.5 | 0.3 | 1 | 197 | 284 | 172 | 435 |
| EN 1276 (2,1) | Bactericide | 0.3 | 0.7  (*E.hirae* instead of *P.aeruginosa* and *E.coli*) | 0.2 | 0.5  (*E.hirae*) | 204 | 397 (*E.hirae*) | 115 | 218 (*E.hirae*) |
| EN 1650 (2,1) | Fungicide | 1 | 1.5 | 1 | 1.5 | 658 | 851 | 573 | 653 |
| Yeasticide | 0.3 | 0.3 | 0.2 | 0.5 | 197 | 170 | 115 | 218 |

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 1, dirty conditions

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Test method/ Product Name** | | **OXE ALCA** | **OXE ALCA (T+6 month)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T+6 month)** | **OXE ALCA** | **OXE ALCA (T+6 month)** | **OXE ALCA CHLORE MOUSSANT** | **OXE ALCA CHLORE MOUSSANT (T+6 month)** |
| **Soiling conditions: dirty** | | **Minimum effective dose expressed as % of product** | | | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | | |
| EN 13697 - 5 min – 3 g/L BSA (2,2) | Bactericide | 1.5 | 6 (*E.hirae*) | 3 | 4 (*E.hirae*) | 987 | 3402 (*E.hirae*) | 1718 | 1741 (*E.hirae*) |
| EN 13697 - 15 min – 3 g/L BSA (2,2) | Fungicide | 3 | 5 | 3 | 3 | 1973 | 2836 | 1718 | 1305 |
| Yeasticide | 1 | 1.5 | 1.5 | 3 | 658 | 851 | 859 | 1305 |
| EN 1276 (2,1) | Bactericide | 1 | 1.5 (*E.hirae*) | 1 | 2 (*E.hirae*) | 681 | 851 (*E.hirae*) | 573 | 870 (*E.hirae*) |
| EN 1650 (2,1) | Fungicide | 1.5 | 2.5 | 2 | 2.5 | 987 | 1418 | 1145 | 1088 |
| Yeasticide | 1 | 1.5 | 1 | 2 | 658 | 851 | 573 | 870 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **META-SPC 1 – OXE ALCA CHLORE MOUSSANT – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *Pseudomonas aeruginosa*  *Escherichia coli*  *Enterrococcus hirae*  *Staphylocoque aureus* | EN NF 1276  Phase 2 step 1 test | Concentration tested: 0.1% v/v; 0.2% v/v; 0.3% v/v (fresh product)  0.3% v/v; 0.5% v/v; 0.7% v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.2% v/v (equivalent to 0.01% or 115 mg/l of active chlorine (a.c.)) | Laboratoire Solutio 1276 propreté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.5% v/v (i.e. 0.019% or 218 mg/l of a.c.) | Laboratoire Solutio 1276 propreté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 0.1% v/v; 0.2% v/v; 0.3% v/v (fresh product)  0.3% v/v; 0.4% v/v; 0.5% v/v (aged product)  Temperature:  18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 0.3% v/v (i.e. 0.015% or 172 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.5% v/v (i.e. 0.019% or 218 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| Yeasticide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *Candida albicans* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 0.1% v/v; 0.2% v/v; 0.3% v/v (fresh product)  0.3% v/v; 0.5% v/v; 0.7% v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.2% v/v (i.e. 0.01% or 115 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 0.5% v/v (i.e. 0.019% or 218 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.1% v/v; 0.2% v/v; 0.3% v/v (fresh product)  0.5% v/v; 1% v/v; 1.5% v/v (aged product)  Temperature:  18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 0.3% v/v (i.e. 0.015% or 172 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.038% or 435 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| Fungicide | PT4-desinfection of hard surfaces and disinfection by soaking | OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *Aspergillus brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.5% v/v; 1% v/v; 1.5% v/v (fresh product)  1.0% v/v; 1.5% v/v; 2.0% v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 1% v/v (i.e. 0.05% or 573 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 1.5% v/v (i.e. 0.05% or 653 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 1% v/v; 2% v/v; 3% v/v (fresh product)  2% v/v; 3% v/v; 4% v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.1% or 1145 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 3% v/v (i.e. 0.114% or 1305 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| **META-SPC 1 – OXE ALCA CHLORE MOUSSANT – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276  Phase 2 step 1 test | Concentration tested: 0.5% v/v; 1% v/v; 1.5% v/v (fresh product)  1.5% v/v; 2% v/v; 3% v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 1% v/v (equivalent to 0.05% or 573 mg/l of active chlorine (a.c.)) | Laboratoire Solutio 1276 saleté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 2% v/v (i.e. 0.076% or 870 mg/l of a.c.) | Laboratoire Solutio 1276 saleté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 1% v/v; 2% v/v; 3% v/v (fresh product)  3% v/v; 4% v/v; 5% v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 3% v/v (i.e. 0.15% or 1718 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 4% v/v (i.e. 0.152% or 1741 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| Yeasticide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *C. albicans* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 0.5% v/v; 1% v/v; 1.5% v/v (fresh product)  1% v/v; 1.5% v/v; 2% v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.05% or 573 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 2% v/v (i.e. 0.076% or 870 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 1% v/v; 1.5% v/v; 2% v/v (fresh product)  2% v/v; 2.5% v/v; 3% v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1.5% v/v (i.e. 0.075% or 859 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 3% v/v (i.e. 0.114% or 1305 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| Fungicide | PT4-desinfection of hard surfaces and disinfection by soaking | OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *Aspergillus brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 1% v/v; 1.5% v/v; 2% v/v (fresh product)  2% v/v; 2.5% v/v; 3% v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.1% or 1145 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 2.5% v/v (i.e. 0.095% or 1088 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (5.0% w/w active chlorine) | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 1% v/v; 2% v/v; 3% v/v (fresh product)  2% v/v; 2.5% v/v; 3% v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 3% v/v (i.e. 0.15% or 1718 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA CHLORE MOUSSANT  RI=1 |
| OXE ALCA CHLORE MOUSSANT  (3.8% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 3% v/v (i.e. 0.114% or 1305 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA CHLORE MOUSSANT T6  RI=1 |
| **META-SPC 1 – OXE ALCA – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 6.0% w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.1% v/v ; 0.2% v/v ; 0.3% v/v (fresh product)  0.3% v/v; 0.5% v/v; 0.7%v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.3% v/v (i.e. 0.018% or 204 mg/l of a.c.)  The least sensible organisms are *P. aeruginosa* and *E. coli*. | Laboratoire Solutio 1276 propreté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.7% v/v (i.e. 0.035% or 397 mg/l of a.c.) | Laboratoire Solutio 1276 propreté OXE ALCA T6  RI=2, the test organism chosen is not the least sensible. |
| OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.1% v/v ; 0.2% v/v ; 0.3% v/v(fresh product)  0.3% v/v; 0.4% v/v; 0.5%v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 0.3% v/v (i.e. 0.0174% or 197 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.5% v/v (i.e. 0.025% or 284 mg/l of active chlorine) | Laboratoire Solutio 13697 propreté OXE ALCA T6  RI=1 |
| Yeasticide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.1% v/v ; 0.2% v/v; 0.3%v/v (fresh product)  0.2% v/v; 0.3% v/v; 0.4%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.3% v/v (i.e. 0.0174% or 197 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 0.3% v/v (i.e. 0.015% or 170 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA T6  RI=1 |
| OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.1% v/v ; 0.2% v/v ; 0.3% v/v (fresh product)  0.3% v/v; 0.5% v/v; 1%v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 0.3% v/v (i.e. 0.0174% or 197 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 0.5% v/v (i.e. 0.025% or 284 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA T6  RI=1 |
| Fungicide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.5% v/v ; 1% v/v; 1.5% v/v (fresh product)  1% v/v; 1.5% v/v; 2%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 1% v/v (i.e. 0.058% or 658 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 1.5% v/v (i.e. 0.075% or 851 mg/l of a.c.) | Laboratoire Solutio 1650 propreté OXE ALCA T6  RI=1 |
| OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 1% v/v; 2% v/v ; 3% v/v (fresh product)  2% v/v; 3% v/v; 4%v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.116% or 1316 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 3% v/v (i.e. 0.15% or 1701 mg/l of a.c.) | Laboratoire Solutio 13697 propreté OXE ALCA T6  RI=1 |
| **META-SPC 1 – OXE ALCA – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 6.0% w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.5% v/v ; 0.8% v/v ; 1% v/v (fresh product)  1% v/v; 1.5% v/v; 2%v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 1% v/v (i.e. 0.060% or 681 mg/l of a.c.) | Laboratoire Solutio 1276 saleté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.075% or 851 mg/l of a.c.) | Laboratoire Solutio 1276 saleté OXE ALCA T6  RI=1 |
| OXE ALCA  (5.6% w/w active chlorine)  6-month aged | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.084% or 953 mg/l of a.c.) | Laboratoire Solutio 1276 saleté OXE ALCA T6  RI=1 |
| OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v(fresh product)  4% v/v; 5% v/v; 6%v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.087% or 987 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 6% v/v (i.e. 0.3% or 3402 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA T6  RI=1 |
| Yeasticide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.5% v/v ; 1% v/v; 1.5%v/v (fresh and product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.058% or 658 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 1.5% v/v (i.e. 0.075% or 851 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA T6  RI=1 |
| OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v; 1.5%v/v (fresh product)  1% v/v; 1.5% v/v; 2%v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.058% or 658 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 1.5% v/v (i.e. 0.075% or 851 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA T6  RI=1 |
| Fungicide | PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 1% v/v; 1.5% v/v; 2% v/v (fresh product)  2% v/v; 2.5% v/v; 3%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 1.5% v/v (i.e. 0.087% or 987 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 2.5% v/v (i.e. 0.125% or 1418 mg/l of a.c.) | Laboratoire Solutio 1650 saleté OXE ALCA T6  RI=1 |
| OXE ALCA  (6.3% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 5.8% w/w | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 2% v/v; 3% v/v; 4% v/v (fresh product)  3% v/v; 4% v/v; 5%v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 3% v/v (i.e. 0.174% or 1973 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA  RI=1 |
| OXE ALCA  (5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 5% v/v (i.e. 0.25% or 2836 mg/l of a.c.) | Laboratoire Solutio 13697 saleté OXE ALCA T6  RI=1 |

BSA: Bovine Serum Albumine

a.c.: active chlorine

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| **Conclusion on the efficacy for the meta SPC 1** |
| For meta SPC 1, tests were performed with formulations OXE ALCA and OXE ALCA CHLORE MOUSSANT. The application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted for each product (phase 2 step 1 test versus phase 2 step 2 test, fresh product versus aged product). Therefore for some uses, activities or target organisms claimed, the application rate validated are higher than claimed and then restrictions in the use conditions are applied.   |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Product** | **PT** | **Field of use envisaged** | **Target organism** | **Soiling conditions** | | **Contact time** | **Application rate claimed**  **in % of product**  **(*mg/L of active chlorine*)** | **Effective concentration in % of product**  **(*mg/L of active chlorine in the test product*)** | | **Validated application rate**  **in % of product**  **(*mg/L of active chlorine*)** | **Conclusion on the use** | | Fresh | 6-month aged | | OXE ALCA  (6.3% a.c.) | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring | Mandatory:  Bacteria  Yeasts | Clean | | 15 min | 0.6% v/v  (*400 mg/L*) | 0.3% v/v  (*204 mg/L*) | 0.7% v/v  (*397 mg/L*) | 0.7%  (*500 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | | Dirty | 15 min | 5.2% v/v  (*3300 mg/L*) | 1.5% v/v  (*987 mg/L*) | 6%% v/v  (*3402 mg/L)* | 6% v/v  (*4287 mg/L) mg/L*) | Validated | | Optional:  Fungal spores | | Clean | 15 min | 3% v/v  (*1650 mg/L*) | 2% v/v  (*1316 mg/L*) | 3% v/v  (*1701 mg/L*) | 3%  (*2144 mg/L*) | Validated | | Optional:  Fungal spores | | Dirty | 15 min | 4.4% v/v  (*2750 mg/L*) | 3% v/v  (*1973 mg/L*) | 5% v/v  (*2836 mg/L*) | 5% v/v  (*3572 mg/L*) | Validated | | # 8 - Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) with circulation | Mandatory:  Bacteria  Yeasts | | Clean | 15 min | 0.6% v/v  (*400 mg/L*) | 0.3% v/v  (*204 mg/L*) | 0.7% v/v  (*397 mg/L*) | 0.7%  (*500 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | | Dirty | 15 min | 5.2% v/v  (*3300 mg/L*) | 1% v/v  (*681 mg/L*) | 1.5% v/v  (*953 mg/L*) | 5.2% v/v  (*3715 mg/L*) | Validated | | Optional:  Fungal spores | | Clean | 15 min | 3% v/v  (*1650 mg/L*) | 1% v/v  (*658 mg/L*) | 1.5% v/v  (*851 mg/L*) | 3%  (2144 *mg/L*) | Validated | | Optional:  Fungal spores | | Dirty | 15 min | 4.4% v/v  (*2750 mg/L*) | 1.5% v/v  (*987 mg/L*) | 2.5% v/v  (*1418 mg/L*) | 4.4% v/v  (*3144 mg/L*) | Validated | | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) | Bacteria  Yeasts  Fungal spores | | Clean  Dirty |  |  |  |  |  | Not validated, no phase 3 test submitted | | # 9 - Disinfection of inner surfaces in veterinary water systems by pouring | Mandatory:  Bacteria | Clean | | 5 min | 0.45% v/v  (*275 mg/L*) | 0.3% v/v  (*204 mg/L*) | 0.7% v/v  (*397 mg/L*) | 0.7% v/v  (500 *mg/L*) | Validated | | Mandatory:Bacteria | Dirty | | 5 min | 5.2% v/v  (*3300 mg/L*) | 1.5% v/v  (*987 mg/L*) | 6% v/v  (*3402 mg/L*) | 6% v/v  (*4287 mg/L*) | Validated | | Optional:  Yeast | Clean | | 15 min | 0.6% v/v  (*400 mg/L*) | 0.3% v/v  (*197 mg/L*) | 0.5% v/v  (*284 mg/L*) | 0.6% v/v  (*429 mg/L*) | Validated | | Optional:  Yeast | Dirty | | 15 min | 1.9% v/v  (*1200 mg/L*) | 1% v/v  (*658 mg/L*) | 1.5% v/v  (*851 mg/L*) | 1.9% v/v  (*1358 mg/L*) | Validated | | Optional:  Fungal spores | Clean | | 15 min | 3% v/v  (*1650 mg/L*) | 2% v/v  (*1316 mg/L*) | 3% v/v  (*1701 mg/L*) | 3% v/v  (*2144 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | | 15 min | 4.4% v/v  (*2750 mg/L*) | 3% v/v  (*1973 mg/L*) | 5% v/v  (*2836 mg/L*) | 5% v/v  (*3572 mg/L*) | Validated | | OXE ALCA CHLORE MOUSSANT  (5% active chlorine) | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring | Mandatory:  Bacteria  Yeasts | Clean | | 15 min | 0.8% v/v  (*400 mg/L*) | 0.3% v/v  (*172 mg/L*) | 1% v/v  (*435 mg/L*) | 1% v/v  (*573 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | | 15 min | 6.6% v/v  (*3300 mg/L*) | 3% v/v  (*1718 mg/L*) | 4% v/v  (*1741 mg/L*) | 6.6% v/v  (*3779 mg/L*) | Validated | | Optional:  Fungal spores | Clean | | 15 min | 3.3% v/v  (*1650 mg/L*) | 2% v/v  (*1145 mg/L*) | 3% v/v  (*1305 mg/L*) | 3.3% v/v  (*1889 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | | 15 min | 5.5% v/v  (*2750 mg/L*) | 3% v/v  (*1718 mg/L*) | 3% v/v  (*1305 mg/L*) | 5.5% v/v  (*3149 mg/L*) | Validated | | # 8 - Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) with circulation | Mandatory:  Bacteria  Yeasts | Clean | | 15 min | 0.8% v/v  (*400 mg/L*) | 0.2% v/v  (*115 mg/L*) | 0.5% v/v  (*218 mg/L*) | 0.8% v/v  (*458 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | | 15 min | 6.6% v/v  (*3300 mg/L*) | 1% v/v  (*573 mg/L*) | 2% v/v  (*870 mg/L*) | 6.6% v/v  (*3779 mg/L*) | Validated | | Optional:  Fungal spores | Clean | | 15 min | 3.3% v/v  (*1650 mg/L*) | 1% v/v  (573 *mg/L*) | 1.5% v/v  (*653 mg/L*) | 3.3% v/v  (*1889 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | | 15 min | 5.5% v/v  (*2750 mg/L*) | 2% v/v  (*1145 mg/L*) | 2.5% v/v  (*1088 mg/L*) | 5.5% v/v  (*3149 mg/L*) | Validated | | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) | Bacteria  Yeasts  Fungal spores | Clean  Dirty | |  |  |  |  |  | Not validated, no phase 3 test submitted | | # 9 - Disinfection of inner surfaces in veterinary water systems by pouring | Mandatory:  Bacteria | Clean | | 5 min | 0.55% v/v  (*275 mg/L*) | 0.3% v/v  (*172 mg/L*) | 0.5% v/v  (*218 mg/L*) | 0.55% v/v  (*315 mg/L*) | Validated | | Mandatory:  Bacteria | Dirty | | 5 min | 6.6% v/v  (*3300 mg/L*) | 3% v/v  (*1718 mg/L*) | 4% v/v  (*1741 mg/L*) | 6.6% v/v  (*3779 mg/L*) | Validated | | Optional:  Yeast | Clean | | 15 min | 0.8% v/v  (*400 mg/L*) | 0.3% v/v  (*172 mg/L*) | 1% v/v  (*435 mg/L*) | 0.8% v/v  (*458 mg/L*) | Validated | | Optional:  Yeast | Dirty | | 15 min | 2.4% v/v  (*1200 mg/L*) | 1.5% v/v  (*859 mg/L*) | 3% v/v  (*1305 mg/L*) | 3% v/v  (*1718 mg/L*) | Validated | | Optional:  Fungal spores | Clean | | 15 min | 3.3% v/v  (*1650 mg/L*) | 2% v/v  (*1145 mg/L*) | 3% v/v  (*1305 mg/L*) | 3.3% v/v  (*1889 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | | 15 min | 5.5% v/v  (*2750 mg/L*) | 3% v/v  (*1718 mg/L*) | 3% v/v  (*1305 mg/L*) | 5.5% v/v  (*3149 mg/L*) | Validated |   Regarding use #5 “disinfection of hard surfaces”, for scrubbing/mopping/wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted but mechanical action is claimed in the submitted SPC. Therefore the eCA consider that wiping/mopping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by spraying/wiping/mopping/pouring followed after the contact time by a mechanical action such as scrubbing wiping/mopping if needeed. A specific instruction for use is added in the SPC.  Regarding use #6 “disinfection of equipment/materials by automatic spraying in closed systems (tunnels)”, in absence of further details provided by the applicant, eCA considered it equivalent to “Disinfection in dishwashing machines and crate washers”. However for this use, for all test organisms phase 2 step 1 tests, phase 2 step 2 tests and phase 3 tests are required. In the absence of phase 3 tests, efficacy for this use is not demonstrated.  Regarding use #8 ” Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP): -for applications in milk and dairy production and milking parlour systems, no specific soiling condition (10 g/L skimmed milk) has been tested. Therefore, efficacy for these uses is not validated in dirty conditions, disinfection has to be performed only in clean conditions. A specific instruction for use has to be added in the SPC.  Conclusion regarding the validation of the efficacy of Meta-SPC 1:  When comparing tests results expressed in mg/L active chlorine obtained for both test formulations OXE ALCA and OXE ALCA CHLORE MOUSSANT when tested fresh and aged, results obtained in some tests are quite different under the same test conditions. Thus, efficacy is different between formulations of the same META-SPC, thus variations of the co-formulants (notably the surfactants) have an impact on efficacy. Therefore, efficacy of the whole META-SPC 1 is validated for the uses for which a common data set is available between the tested products OXE ALCA (fresh and aged product) and OXE ALCA CHLORE MOUSSANT (fresh and aged product). The worst case (highest effective active chlorine concentration covering all tested products) is taken into account to validate the active chlorine efficient dose.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | PT | Uses | User category | Target organism | Soiling conditions | Contact time  (min) | Worst case application rate in mg/L of active chlorine to be validated for the meta-SPC | | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring | PRO & IND | Mandatory :  Bacteria  Yeasts | Clean | 15 | 573 mg/L | | Mandatory :  Bacteria  Yeasts | Dirty | 15 | 4287mg/L | | Optional:  Fungal spores | Clean | 15 | 2144 mg/L | | Optional: Fungal spores | Dirty | 15 | 3572 mg/L | | # 8 - Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) by pouring | PRO & IND | Mandatory:  Bacteria  Yeasts | Clean | 15 | 500 mg/L | | Mandatory:  Bacteria  Yeasts | Dirty | 15 | 3779 mg/L | | Optional: Fungal spores | Clean | 15 | 2144 mg/L | | Optional: Fungal spores | Dirty | 15 | 3149 mg/L | | # 6 - Disinfection of equipment/ materials by automatic spraying in closed systems (tunnels) | PRO & IND | Bacteria Yeasts Fungal spores | Clean Dirty |  | Not validated, no phase 3 test submitted | | # 9 - Disinfection of inner surfaces in veterinary water systems by pouring | PRO & IND | Mandatory: Bacteria | Clean | 5 | 500 mg/L | | Mandatory: Bacteria | Dirty | 5 | 4287mg/L | | Optional: Yeast | Clean | 15 | 458 mg/L | | Optional: Yeast | Dirty | 15 | 1718 mg/L | | Optional: Fungal spores | Clean | 15 | 2144 mg/L | | Optional: Fungal spores | Dirty | 15 | 3572 mg/L |   In the SPC, if needed, mandatory and optional target organisms have been grouped with regard to the worst case application rate and contact time. |

**2) Meta-SPC 2 – Bleach 9.6 - 12.5% professional:**

PT2 use#1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) (Non medical sector and medical sector)

PT2 use#2 - Disinfection of hard surfaces (non medical sector)

PT2 use#3 - Disinfection of hard surfaces (medical sector) (only for the product Bleach 9.6%)

PT2 use#6 – Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) (Non medical sector and medical sector)

PT2 use#7 - Disinfection of equipment/materials by immersion/dipping/soaking (Non medical sector)

PT4 use#5 - Disinfection of hard surfaces

PT4 use#6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)

PT4 use#7 - Disinfection of equipment/materials by immersion/dipping/soaking

PT4 use#8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP)

PT4 use#9 - Disinfection of surfaces of inner surfaces in veterinary water systems

META-SPC 2 contains products to be diluted containing active chlorine between 9.6 and 12.5 % w/w, and no coformulants in the composition.

Efficacy studies were performed on 2 formulations, JAVEL 12.5 PRO OXENA (12.5 % w/w active chlorine) and JAVEL 9.6 PRO OXENA (9.6% w/w active chlorine), to cover the efficacy of the whlole META SPC2.

For the specific uses in dirty conditions related to medical area (uses #3, #1, #6), read across with META SPC 3 has been proposed by the applicant. Tests have been performed with representative products JAVEL 2.6 PRO OXENA (only active chlorine); JAVEL 2.6 Citron PRO OXENA (active chlorine + negligible quantity of surfactant) and JAVEL 2.6 detergence citron PRO OXENA (active chlorine + sequestrant).

For virucidal activity, whatever the use, read across with META SPC 3 is made with tests performed with the product JAVEL 2.6 PRO OXENA (only active chlorine).

Phase 2 step 1 and phase 2 step 2 tests were performed with bacteria, yeasts, fungal spores, and virus (EN 1276, 1650, EN 13624, EN 14476 and EN 13697, 20°C, 5 and 15 min contact times, clean and dirty conditions).

Moreover, as significant decrease of the active substance is observed for JAVEL 12.5 PRO OXENA during long-term storage stability study (-39 % after 5 months, corresponding to 8.3% m/v of active chlorine), efficacy tests were also performed on a 6-month aged formulation of JAVEL 12.5 PRO OXENA. However it has to be noted that a worst case for efficacy assessment should have been to test the formulation containing the less active chlorine concentration thus JAVEL 9.6 PRO OXENA.

Indeed, according to the Technical Agreements for Biocides (TAB, point 12), if the active substance concentration decreases with more than 10 % during the claimed shelf-life, test can be performed only with the claimed organism most difficult to kill (based on the fresh product data) with aged product that has been stored for the complete claimed shelf life to support the efficacy for the claimed shelf-life. Then in order to demonstrate the bactericidal activity of aged products, tests have been submitted only on *Enterococcus hirae*. Except for tests according to EN1276, *E.hirae* has been demonstrated to be the bacterium the most difficult to kill. As for the fresh product, the tests according to EN 13697 in clean and dirty conditions demonstrate that *E.hirae* is the most difficult to kill, the EN1276 in clean and dirty conditions performed on *E.hirae* with the aged product has been considered acceptable.

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 2, clean conditions.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test method/ Product Name** | | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6 mois)** | **Javel 9,6 PRO OXENA** | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6 mois)** | **Javel 9,6 PRO OXENA** |
| **Soiling conditions: Clean** | | **Minimum effective dose expressed as % of product** | | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | |
| EN 13697 - 5 min – 0.3 g/L BSA (2,2) | Bactericide | 0.4 | 0.4  (*E.hirae*) | 0.5 | 562 | 315  (*E.hirae*) | 552 |
| EN 13697 - 15 min – 0.3 g/L BSA (2,2) | Fungicide | 0.8 | 1.5 | 0.8 | 1123 | 1180 | 883 |
| Yeasticide | 0.2 | 1 | 0.5 | 281 | 787 | 552 |
| EN 1276 (2,1) | Bactericide | 0.2 | 0.3  (*E.hirae* instead of *P.aeruginosa*) | 0.2 | 286 | 236  (*E.hirae* instead of *P.aeruginosa*) | 221 |
| EN 1650 (2,1) | Fungicide | 0.6 | 1.5 | 0.8 | 857 | 1180 | 883 |
| Yeasticide | 0.1 | 0.5 | 0.1 | 143 | 394 | 110 |

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 2, dirty conditions.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test method/ Product Name** | | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6 mois)** | **Javel 9,6 PRO OXENA** | **Javel 12,5 PRO OXENA** | **Javel 12,5 PRO OXENA (T +6 mois)** | **Javel 9,6 PRO OXENA** |
| **Soiling conditions: Dirty** | | **Minimum effective dose expressed as % of product** | | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | |
| EN 13697 - 5 min - 3 g/L BSA (2,2) | Bactericide | 1.5 | 3  (*E.hirae*) | 1.5 | 2106 | 2361  (*E.hirae*) | 1656 |
| EN 13697 - 15 min - 3 g/L BSA (2,2) | Fungicide | 2 | 4 | 2 | 2809 | 3148 | 2208 |
| Yeasticide | 1 | 1.5 | 1 | 1404 | 1180 | 1104 |
| EN 1276 (2,1) | Bactericide | 0.8 | 1  (*E.hirae* instead of *P.aeruginosa*) | 0.8 | 1143 | 787  (*E.hirae* instead of *P.aeruginosa*) | 883 |
| EN 1650 (2,1) | Fungicide | 1.5 | 3 | 1.9 | 2143 | 2361 | 2098 |
| Yeasticide | 0.7 | 1 | 0.8 | 1000 | 787 | 883 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **META-SPC 2 – Javel 12.5% – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.8% w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.05% v/v ; 0.1% v/v ; 0.2% v/v (fresh product)  0.2% v/v; 0.3% v/v; 0.4%v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.2% v/v (i.e. 0.0236% or 286 mg/l of a.c.)  The least sensible organism is *P. aeruginosa*. | Laboratoire Solutio 1276 propreté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.3% v/v (i.e. 0.0195% or 236 mg/l of a.c.) | Laboratoire Solutio 1276 propreté JAVEL 12.5 T6  RI=3 |
| Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.6 % w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.1% v/v ; 0.2% v/v ; 0.4% v/v(fresh product)  0.3% v/v; 0.4% v/v; 0.5%v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 0.4% v/v (i.e. 0.0464% or 562 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.4% v/v (i.e. 0.026% or 315 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 12.5 T6  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.8% w/w | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.05% v/v ; 0.1% v/v (fresh product)  0.2% v/v; 0.4% v/v; 0.5%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.1% v/v (i.e. 0.0118% or 143 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 0.5% v/v (i.e. 0.0325% or 394 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 12.5 T6  RI=1 |
| Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.6 % w/w | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.1% v/v ; 0.2% v/v ; 0.4% v/v(fresh product)  0.8% v/v; 1% v/v; 1.5%v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 0.2% v/v (i.e. 0.0232% or 281 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.065% or 787 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 12.5 T6  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.8 % w/w | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.3% v/v ; 0.6% v/v (fresh product)  0.6% v/v; 1% v/v; 1.5%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 0.6% v/v (i.e. 0.0708% or 857 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 1.5% v/v (i.e. 0.0975% or 1180 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 12.5 T6  RI=1 |
| Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.6% w/w | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.6% v/v ; 0.8% v/v ; 0.9% v/v (fresh product)  0.8% v/v; 1% v/v; 1.5%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 0.8% v/v (i.e. 0.0928% or 1123 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 1.5% v/v (i.e. 0.0975% or 1180 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 12.5 T6  RI=1 |
| **META-SPC 2 – Javel 12.5% – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.8% w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.7% v/v ; 0.8% v/v (fresh product)  0.8% v/v; 1% v/v; 1.5%v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.8% v/v (i.e. 0.0944% or 1143 mg/l of a.c.)  The least sensible organisms are *P. aeruginosa* and *E. coli*. | Laboratoire Solutio 1276 saleté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 1% v/v (i.e. 0.065% or 787 mg/l of a.c.) | Laboratoire Solutio 1276 saleté JAVEL 12.5 T6  RI=2 |
| Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.6 % w/w | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v(fresh product)  2% v/v; 2.5% v/v; 3%v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.174% or 2106 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | *E. hirae* | Bactericidal activity demonstrated at 3% v/v (i.e. 0.195% or 2361 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 12.5 T6 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.8% w/w | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.6% v/v ; 0.7% v/v (fresh product)  0.8% v/v; 1% v/v; 1.5%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.7% v/v (i.e. 0.0826% or 1000 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.065% or 787 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 12.5 T6  RI=1 |
| Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.6 % w/w | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v(fresh product)  1% v/v; 1.5% v/v; 2%v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.116% or 1404 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Yeasticidal activity demonstrated at 1.5% v/v (i.e. 0.0975% or 1180 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 12.5 T6  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.8 % w/w | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 1% v/v ; 1.5% v/v (fresh product)  2% v/v; 3% v/v; 4%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 1.5% v/v (i.e. 0.177% or 2143 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 3% v/v (i.e. 0.195% or 2361 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 12.5 T6  RI=1 |
| Javel 12.5%  (12.5% w/w active chlorine)  -> active chlorine concentration at the beginning of the test : 11.6% w/w | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 1% v/v ; 1.5% v/v ; 2% v/v (fresh product)  2% v/v; 3% v/v; 4%v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.232% or 2809 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 12.5  RI=1 |
| Javel 12.5%  (6.5% w/w active chlorine)  6-month aged | Fungicidal activity demonstrated at 4% v/v (i.e. 0.26% or 3148 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 12.5 T6  RI=1 |
| **META-SPC 2 – Javel 9.6% – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 9.6%  (9.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.1% v/v ; 0.2% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.2% v/v (i.e. 0.0192% or 221 mg/l of a.c.) | Laboratoire Solutio 1276 propreté Javel 9.6%  RI=1 |
| EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.2% v/v ; 0.5% v/v ; 0.8% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 0.5% v/v (i.e. 0.048% or 552 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 9.6  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 9.6%  (9.6% w/w active chlorine) | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested:  0.05% v/v ; 0.1% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.1% v/v (i.e. 0.0096% or 110 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 9.6%  RI=1 |
| EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.2% v/v ; 0.5% v/v ; 0.8% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 0.5% v/v (i.e. 0.048% or 552 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 9.6  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 9.6%  (9.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.4% v/v ; 0.8% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 0.8% v/v (i.e. 0.0768% or 883 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 9.6%  RI=1 |
| EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 0.8% v/v ; 1% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 0.8% v/v (i.e. 0.0768% or 883 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 9.6  RI=1 |
| **META-SPC 2 – Javel 9.6% – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 9.6%  (9.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.7% v/v ; 0.8% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.8% v/v (i.e. 0.0768% or 883 mg/l of active chlorine) | Laboratoire Solutio 1276 saleté Javel 9.6%  RI=1 |
| EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.144% or 1656 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 9.6  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 9.6%  (9.6% w/w active chlorine) | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested:  0.5% v/v ; 0.8% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.8% v/v (i.e. 0.0768% or 883 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 9.6%  RI=1 |
| EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.096% or 1104 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 9.6  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 9.6%  (9.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 1.7% v/v ; 1.9% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 1.9% v/v (i.e. 0.1824% or 2098 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 9.6%  RI=1 |
| EN NF 13697 Phase 2 step 2 test | Concentration tested: 1% v/v ; 1.5% v/v ; 2% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.192% or 2208 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 9.6  RI=1 |

BSA: Bovine Serum Albumine

a.c.: active chlorine

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| --- |
| **Conclusion on the efficacy for the meta SPC 2** |
| For meta SPC 2 tests were performed with formulations JAVEL 12.5 PRO OXENA and JAVEL 9.6 PRO OXENA.  Read across with META SPC 3 for medical uses and virucidal activity has been proposed by the applicant but not accepted by the eCA. Indeed, according to the applicant, the product Javel 9.6 PRO OXENA is intended to be systematically diluted to obtain a solution at a concentration of 2.6% of active chlorine that is the concentration of active chlorine in META SPC 3. However, when comparing compositions of META-SPC 2 and META-SPC 3 and test results expressed in mg/L active chlorine obtained for the formulations of META-SPC 2 and META-SPC 3, it can be concluded that, in the majority of the tests, results obtained are different under same test conditions. Thus, read across between META SPC 2 and 3 cannot be accepted and efficacy against bacteria, fungi and yeasts for uses in healthcare (use #1 and use #3) in dirty conditions, is not demonstrated for META-SPC 2.  Regarding virucidal activity, the applicant proposes also a read across with META-SPC 3, laboratory suspension tests were performed with viruses (EN 14476, 20°C, 15 min contact time, dirty conditions) with JAVEL 2.6. However, for the reasons stated above, read across between META SPC 2 and 3 cannot be accepted and virucidal efficacy is not demonstrated for META-SPC 2.  The application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted for each product (phase 1 step 1 test versus phase 2 step 2 test, fresh product versus aged product). Therefore for some uses, activities or target organisms claimed, the application rates validated are higher than claimed and then restrictions in the use conditions are applied.   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Product** | **PT** | **Field of use envisaged** | **Target organisms** | **Soiling conditions** | **Contact time** | **Application rate claimed in**  **% of product**  **(*mg/L of active chlorine*)** | **Effective concentration**  **in % of product**  **(*mg/L of active chlorine in the test product*)** | | **Validated application rate in % of product**  **(*mg/L of active chlorine*)** | **Conclusion on the use** | | Fresh | 6-month aged | | JAVEL 9.6 PRO OXENA (9.6% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector  # 2 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Non medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Non medical sector | Mandatory:  Bacteria | Clean | 5 min | 0.5% v/v  (*470 mg/L*) | 0.5% v/v  (*552 mg/L*) |  | 0.5% v/v  (552 *mg/L*) | Validated | | Mandatory:  Bacteria | Dirty | 5 min | 2.6% v/v  (*2490 mg/L*) | 1.5% v/v  (*1650 mg/L*) |  | 2.6% v/v  (*2870 mg/L*) | Validated | | Optional:  Yeasts | Clean | 15 min | 0.9% v/v  (*830 mg/L*) | 0.5% v/v  (*552 mg/L*) |  | 0.9% v/v  (*994 mg/L*) | Validated | | Optional:  Yeasts | Dirty | 15 min | 1.3% v/v  (*1245 mg/L*) | 1% v/v  (*1104 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 1.3% v/v  (*1245 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 3.5% v/v  (*3320 mg/L*) | 2% v/v  (*2208 mg/L*) |  | 3.5% v/v  (*3864 mg/L*) | Validated | | Optional:  Virus | Clean  Dirty |  |  |  |  |  | Not validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 0.9% v/v  (*830 mg/L*) | 0.5% v/v  (*552 mg/L*) |  | 0.9% v/v  (*994 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 1.3% v/v  (*1245 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | 2 | # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 0.4% v/v  (*390 mg/L*) | 0.5% v/v  (*552 mg/L*) |  | 0.5% v/v  (*552 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 1.1% v/v  (*1040 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 1.1% v/v  (*1214 mg/L*) | Validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector  # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Dirty |  |  |  |  |  | Not validated | | 2 and 4 | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  Non medical and Medical sector | Bacteria  Yeast  Fungal spores  Viruses | Clean  Dirty |  |  |  |  |  | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring  # 7 - Disinfection of equipment/materials by immersion/soaking  Food and feed area  Non-medical sector | Bacteria  Yeasts | Clean | 15 min | 0.9% v/v  (*830 mg/L*) | 0.5% v/v  (*552 mg/L*) |  | 0.9% v/v  (*994 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 2.6% v/v  (*2490 mg/L*) | 1.5% v/v  (*1656 mg/L*) |  | 2.6% v/v  (*2870 mg/L*) | Validated | | Fungal spores | Clean | 15 min | 1.3% v/v  (*1245 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | Fungal spores | Dirty | 15 min | 3.5% v/v  (*3320 mg/L*) | 2% v/v  (*2208 mg/L*) |  | 3.5% v/v  (*3864 mg/L*) | Validated | | Viruses | Dirty | 15 min |  |  |  |  | Not validated | | 4 | # 8  Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  Food and feed area | Bacteria  Yeasts | Clean | 15 min | 0.9% v/v  (*830 mg/L*) | 0.2% v/v  (*552 mg/L*) |  | 0.9% v/v  (*994 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 2.6% v/v  (*2490 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 2.6% v/v  (*2870 mg/L*) | Validated | | Fungal spores | Clean | 15 min | 1.3% v/v  (*1245 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | Fungal spores | Dirty | 15 min | 3.5% v/v  (*3320 mg/L*) | 1.9% v/v  (*2098 mg/L*) |  | 3.5% v/v  (*3864 mg/L*) | Validated | | Viruses | Dirty | 15 min |  |  |  |  | Not validated | | 4 | # 9  Disinfection of inner surfaces in veterinary water systems  Food and feed area | Bacteria | Clean | 5 min | 0.5% v/v  (*470 mg/L*) | 0.5% v/v  (552*mg/L*) |  | 0.5% v/v  (*552 mg/L*) | Validated | | Bacteria | Dirty | 5 min | 2.6% v/v  (*2490 mg/L*) | 1.5% v/v  (*1656 mg/L*) |  | 2.6% v/v  (*2870 mg/L*) | Validated | | Yeast | Clean | 15 min | 0.9% v/v  (*830 mg/L*) | 0.5% v/v  (*552 mg/L*) |  | 0.9% v/v  (*994 mg/L*) | Validated | | Yeast | Dirty | 15 min | 1.3% v/v  (*1245 mg/L*) | 1% v/v  (*1104 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 1.3% v/v  (*1245 mg/L*) | 0.8% v/v  (*883 mg/L*) |  | 1.3% v/v  (*1435 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 3.5% v/v  (*3320 mg/L*) | 2% v/v  (*2208 mg/L*) |  | 3.5% v/v  (*3864 mg/L*) | Validated | | Viruses | Dirty |  |  |  |  |  | Not validated | | JAVEL 12.5 PRO OXENA (12.5% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector  # 2 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Non medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Non medical sector | Bacteria | Clean | 5 min | 0.4% v/v  (*470 mg/L*) | 0.4% v/v  (*562 mg/L*) | 0.4% v/v  (315 *mg/L*) | 0.4% v/v  (*562 mg/L*) | Validated | | Bacteria | Dirty | 5 min | 2% v/v  (*2490 mg/L*) | 1.5% v/v  (*2106 mg/L*) | 3% v/v  (2361 *mg/L*) | 3% v/v  (*4540 mg/L*) | Validated | | Yeast | Clean | 15 min | 0.7% v/v  (*830 mg/L*) | 0.2% v/v  (281 *mg/L*) | 1% v/v  (787 *mg/L*) | 1% v/v  (*1513 mg/L*) | Validated | | Yeast | Dirty | 15 min | 1% v/v  (*1245 mg/L*) | 1% v/v  (*1404 mg/L*) | 1.5% v/v  (1180 *mg/L*) | 1.5% v/v  (*2270 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 1% v/v  (*1245 mg/L*) | 0.8% v/v  (*1123 mg/L*) | 1.5% v/v  (1180 *mg/L*) | 1.5% v/v  (*2270 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 2.6% v/v  (*3320 mg/L*) | 2% v/v  (2809 *mg/L*) | 4% v/v  (3148 *mg/L*) | 4% v/v  (*6053 mg/L*) | Validated | | Viruses | Dirty |  |  |  |  |  | Not validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector | Bacteria  Yeasts | Clean | 15 min | 0.7% v/v  (*830 mg/L*) | 0.4% v/v  (*562 mg/L*) | 1% v/v  (787 *mg/L*) | 1% v/v  (*1513 mg/L*) | Validated | | Fungal spores | Clean | 15 min | 1% v/v  (*1245 mg/L*) | 0.8% v/v  (*1123 mg/L*) | 1.5% v/v  (1180 *mg/L*) | 1.5% v/v  (*2270 mg/L*) | Validated | | 2 and 4 | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  Non medical and medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Clean  Dirty |  |  |  |  |  | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring  # 7 - Disinfection of equipment/materials by immersion/soaking  Food and feed area  Non-medical sector | Bacteria  Yeasts | Clean | 15 min | 0.7% v/v  (*830 mg/L*) | 0.4% v/v  (*562 mg/L*) | 1% v/v  (787 *mg/L*) | 1% v/v  (*1513 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 2% v/v  (*2490 mg/L*) | 1.5% v/v  (*2106 mg/L*) | 3% v/v  (2361 *mg/L*) | 3% v/v  (*4540 mg/L*) | Not validated | | Fungal spore | Clean | 15 min | 1% v/v  (*1245 mg/L*) | 0.8% v/v  (*1123 mg/L*) | 1.5% v/v  (1180 *mg/L*) | 1.5% v/v  (*2270 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 2.6% v/v  (*3320 mg/L*) | 2% v/v  (2809 *mg/L*) | 4% v/v  (3148 *mg/L*) | 4% v/v  (*6053 mg/L*) | Validated | | Viruses | Dirty |  |  |  |  |  | Not validated | | 4 | # 8  Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  Food and feed area | Bacteria  Yeasts | Clean | 15 min | 0.7% v/v  (*830 mg/L*) | 0.2% v/v  (*286 mg/L*) | 0.5% v/v  (394 *mg/L*) | 0.7% v/v  (*1059 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 2% v/v  (*2490 mg/L*) | 0.8% v/v  (*1143 mg/L*) | 1% v/v  (787 *mg/L*) | 2% v/v  (*3027 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 1% v/v  (*1245 mg/L*) | 0.6% v/v  (*857 mg/L*) | 1.5% v/v  (1180 *mg/L*) | 1.5% v/v  (*2270 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 2.6% v/v  (*3320 mg/L*) | 1.5% v/v  (2143 *mg/L*) | 3% v/v  (2361 *mg/L*) | 3% v/v  (*4540 mg/L*) | Validated | | Viruses | Dirty |  |  |  |  |  | Not validated | | 4 | # 9 – Disinfection of inner surfaces in veterinary water systems  Food and feed area | Bacteria | Clean | 5 min | 0.4% v/v  (*470 mg/L*) | 0.4% v/v  (*562 mg/L*) | 0.4% v/v  (315 *mg/L*) | 0.4% v/v  (*562 mg/L*) | Validated | | Bacteria | Dirty | 5 min | 2% v/v  (*2490 mg/L*) | 1.5% v/v  (*2106 mg/L*) | 3% v/v  (2361 *mg/L*) | 3% v/v  (*4540 mg/L*) | Validated | | Yeast | Clean | 15 min | 0.7% v/v  (*830 mg/L*) | 0.1% v/v  (*143 mg/L*) | 0.5%  (394 *mg/L*) | 0.7% v/v  (*1059 mg/L*) | Validated | | Yeast | Dirty | 15 min | 1% v/v  (*1245 mg/L*) | 0.7% v/v  (*1000 mg/L*) | 1%  (*787 mg/L*) | 1% v/v  (*1513 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 1% v/v  (*1245 mg/L*) | 0.6% v/v  (*857 mg/L*) | 1.5% v/v  (1180 *mg/L*) | 1.5% v/v  (*2270 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 2.6% v/v  (*3320 mg/L*) | 1.5% v/v  (2143 *mg/L*) | 3% v/v  (2361 *mg/L*) | 3% v/v  (*4540 mg/L*) | Not validated | | Virus | Dirty | 15 min |  |  |  |  | Not validated |   Regarding PT2 use #1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) (non medical sector and medical sector), PT2 uses # 2 and 3 disinfection of hard surfaces, PT4 uses #5 disinfection of hard surfaces, for scrubbing/mopping/wipping mode of applications, no Phase 2 Step 2 test with mechanical action has been submitted. Therefore eCA concludes that wiping/mopping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by spraying/wiping/mopping/pouring followed after the contact time by a mechanical action such as scrubbing/wiping/mopping if needeed. A specific instruction for use is added in the SPC.  Regarding use #8 ” Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP): -for applications in milk and dairy production and milking parlour systems, no specific soiling condition (10 g/L skimmed milk) has been tested. Therefore, efficacy for these uses is not validated in dirty conditions, disinfection has to be performed only in clean conditions. A specific instruction for use has to be added in the SPC.  Regarding use #6 “disinfection of equipment/materials by automatic spraying in closed systems (tunnels)”, eCA considered it equivalent to “Disinfection in dishwashing machines and crate washers”. However, for this use, for all test organisms phase 2 step 1 tests, phase 2 step 2 tests and phase 3 tests are required. In the absence of phase 3 tests, efficacy for this use is not demonstrated.  Conclusion regarding the validation of the efficacy of Meta-SPC 2:  Taking into account the absence of variation of co-formulants in the products of META-SPC 2, it could be assumed that no impact on efficacy is awaited when only active substance varies. However, when comparing tests results expressed in mg/L active chlorine obtained for both test formulations when tested fresh and aged, it can be concluded that, in some tests, results obtained are different under the same test conditions. Thus, efficacy is different between formulations of the same META-SPC, thus variations of the active substance has no neutral action on efficacy (an explanation could be the reactivity and instability of the active substance in presence of the organic materials). Therefore, efficacy of the whole META-SPC 2 is validated for the uses for wich a common data set is available between the tested products JAVEL 12.5 PRO OXENA (fresh and aged) and JAVEL 9.6 PRO OXENA (fresh product only). The worst case (highest effective active chlorine concentration covering all tested products) is taken into account to validate the active chlorine efficient dose.   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | PT | Uses | Field of use envisaged | User category | Target organisms | Soiling conditions | Contact time | Worst case application rate in mg/L of active chlorine to be validated for the meta-SPC | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring | Non medical sector Indoor | PRO | Mandatory: Bacteria | Clean | 5 min | 562 mg/L | | Mandatory: Bacteria | Dirty | 5 min | 4540 mg/L | | | Optional:  Yeasts | Clean | 15 min | 1513 mg/L | | | Optional:  Yeasts | Dirty | 15 min | 2270 mg/L | | | Optional:  Fungal spores | Clean | 15 min | 2270 mg/L | | | Optional: Fungal spores | Dirty | 15 min | 6053 mg/L | | | Optional: virus | Dirty |  | Not validated | | | Medical sector Indoor | Mandatory: Bacteria, Yeasts | Clean | 15 min | 1513 mg/L | | | Optional: Fungal spores | Clean | 15 min | 2270 mg/L | | | Bacteria Yeasts Fungal spores Viruses | Dirty |  | Not validated | | # 2 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing | Non medical sector Indoor | PRO | Mandatory: Bacteria | Clean | 5 min | 562 mg/L | | | Mandatory: Bacteria | Dirty | 5 min | 4540 mg/L | | | Optional: yeasts | Clean | 15 min | 1513 mg/L | | | Optional: yeasts | Dirty | 15 min | 2270 mg/L | | | Optional: Fungal spores | Clean | 15 min | 2270 mg/L | | | Optional: Fungal spores | Dirty | 15 min | 6053 mg/L | | | Optional: virus | Clean |  | Not validated | | Dirty | | # 7 - Disinfection of equipment/materials by immersion/soaking | Non medical sector Indoor | PRO | Mandatory: Bacteria | Clean | 5 min | 562 mg/L | | | Mandatory: Bacteria | Dirty | 5 min | 4540 mg/L | | | Optional: yeasts | Clean | 15 min | 1513 mg/L | | | Optional: yeasts | Dirty | 15 min | 2270 mg/L | | | Optional: Fungal spores | Clean | 15 min | 2270 mg/L | | | Optional: Fungal spores | Dirty | 15 min | 6053 mg/L | | | Optional: virus | Clean |  | Not validated | | Dirty | | # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing Medical sector | Medical sector Indoor | PRO | Mandatory: Bacteria  Yeasts | Clean | 15 min | 1513 mg/L | | | Optional:  Fungal spores | Clean | 15 min | 2270 mg/L | | | Bacteria Yeasts Fungal spores Viruses | Dirty |  | Not validated | | 2 and 4 | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) | Non medical and Medical sector Indoor | PRO | Bacteria Yeasts Fungal spores Viruses | Clean |  | Not validated | | Bacteria Yeasts Fungal spores Viruses | Dirty | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring |  | PRO | Bacteria Yeasts | Clean | 15 min | 1513 mg/L | | | | Bacteria Yeasts | Dirty | 15 min | 4540 mg/L | | | Fungal spores | Clean | 15 min | 2270 mg/L | | | Fungal spores | Dirty | 15 min | 6053 mg/L | | | Viruses | Dirty | 15 min | Not validated | | # 7 - Disinfection of equipment/materials by immersion/soaking | Food and feed area Non-medical sector | PRO | Bacteria Yeasts | Clean | 15 min | 1513 mg/L | | Bacteria Yeasts | Dirty | 15 min | 4540 mg/L | | | Fungal spores | Clean | 15 min | 2270 mg/L | | | Fungal spores | Dirty | 15 min | 6053 mg/L | | | Viruses | Dirty | 15 min | Not validated | | #8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP). | Food and feed area | PRO | Bacteria Yeasts | Clean | 15 min | 1059 mg/L | | Bacteria Yeasts | Dirty | 15 min | 3027 mg/L | | Fungal spores | Clean | 15 min | 2270 mg/L | | Fungal spores | Dirty | 15 min | 4540 mg/L | | Viruses | Dirty | 15 min | Not validated | | #9- Disinfection of inner surfaces in veterinary water systems | Food and feed area | PRO | Bacteria | Clean | 5 min | 562 mg/L | | Bacteria | Dirty | 5 min | 4540 mg/L | | | Yeast | Clean | 15 min | 1059 mg/L | | | Yeast | Dirty | 15 min | 1513 mg/L | | | Fungal spore | Clean | 15 min | 2270 mg/L | | | Fungal spore | Dirty | 15 min | 4540 mg/L | | | Viruses | Dirty |  | Not validated |   In the SPC, if needed, mandatory and optional target organisms have been grouped with regard to the worst case application rate and contact time. |

**3) Meta-SPC 3 – Bleach 2.6% professional:**

PT2 – use #1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) (Non medical sector and Medical sector) without mechanical action

PT2 – use #2 - Disinfection of hard surfaces (non medical sector) with mechanical action

PT2 – use #3 - Disinfection of hard surfaces (medical sector) with mechanical action

PT2 - use #6 – Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) (Non medical sector and Medical sector) without mechanical action

PT2 – use #7 - Disinfection of equipment/materials by immersion/dipping/soaking (Non medical sector) without mechanical action

PT4 – use #5 -disinfection of hard surfaces with mechanical action

PT4 – use #6 -disinfection of equipment/materials in closed systems (tunnels) without mechanical action

PT4 – use #7 -equipment disinfection by immersion/soaking without mechanical action

PT4 – use #8 -disinfection of inner surface by circulation (CIP)

META-SPC 3 contains products to be diluted containing active chlorine at 2.6 % w/w, with variations of co-formulants.

Efficacy studies were performed on 3 formulations, JAVEL 2.6 PRO OXENA (2.6 % w/w active chlorine without surfactant and without perfume), JAVEL 2.6 DETERGENCE CITRON PRO OXENA (2.6% w/w active chlorine with surfactant and perfume) and JAVEL 2.6 CITRON PRO OXENA (2.6% w/w active chlorine without surfactant and with perfume), in order to evaluate the effect of co-formulants like perfumes or those related to detergent action.

Phase 2 step 1 and/or phase 2 step 2 tests were performed with bacteria, fungal spore, yeasts and viruses (EN 1276, 13727, 1650, 13624, 14476, 13697, 16615, 20°C, 5 and/or 15 min contact time, clean and/or dirty conditions).

Moreover, as significant decrease of the active substance is observed during long-term storage stability study for JAVEL 2.6 DÉTERGENCE CITRON (-24.4% after 12 months, corresponding to 1.83% m/v of active chlorine), efficacy tests were also performed on a 12-month aged formulation of JAVEL 2.6 DETERGENCE CITRON PRO OXENA.

Indeed, according to the Technical Agreements for Biocides (TAB, point 12), if the active substance concentration decreases with more than 10 % during the claimed shelf-life, test can be performed only with the claimed organism most difficult to kill (based on the fresh product data) with aged product that has been stored for the complete claimed shelf life to support the efficacy for the claimed shelf-life. In order to demonstrate the bactericidal activity of aged product tests have been submitted only on *Enterococcus hirae*. Based on data on the fresh products, *E.hirae* has been demonstrated to be the bacterium the most difficult to kill.

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 3, clean conditions.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Test method/ Product Name** | | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA (T +12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** |
| **Soiling conditions: Clean** | | **Minimum effective dose of active chlorine (expressed as % of product)** | | | | | | | | |
| EN 13697 - 5 min (2,2) | Bactericide |  | 1.5 | 2  (*E.hirae*) |  | 1.5 |  |  |  | 1.5 |
| EN 13697 - 15 min (2,2) | Fungicide |  | 4 | 5 |  | 3 |  |  |  | 4 |
| Yeasticide |  | 1 | 1 |  | 1 |  |  |  | 1 |
| NF EN 1276 (2,1) | Bactericide |  | 0.8 | 0.8  (*E.hirae*) |  | 0.5 |  |  |  | 0.5 |
| NF EN 1650 (2,1) | Fungicide |  | 2 | 2 |  | 2 |  |  |  | 2 |
| Yeasticide |  | 0.8 | 0.8 |  | 0.5 |  |  |  | 0.8 |
| EN 13624 (2,1) | Fungicide |  |  |  |  | 2.31 |  |  |  |  |
| Yeasticide |  |  |  |  | 0.31 |  |  |  |  |
| EN 13727 - 15 min (2,1) | Bactericide |  |  |  |  | 0.15 |  |  |  |  |
| EN14476 - 15 min (2,1) | Virucide |  |  |  |  | n/t |  |  |  |  |
| EN 16615 - 5 min (2,2) | Bactericide |  |  |  |  | 1.54 |  |  |  |  |
| Yeasticide |  |  |  |  | 1.54 |  |  |  |  |
| EN 16615 - 15 min (2,2) | Bactericide |  |  |  |  | 0.31 |  |  |  |  |
| Yeasticide |  |  |  |  | 0.31 |  |  |  |  |

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| **Test method/ Product Name** | | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron  PRO OXENA** | **Javel 2,6 detergence citron  PRO OXENA (T +12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** |
| **Soiling conditions: Clean** | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | | | | | | | |
| EN 13697 - 5 min (2,2) | Bactericide |  | 402 | 433  (*E.hirae*) |  | 402 |  |  |  | 403 |
| EN 13697 - 15 min (2,2) | Fungicide |  | 1071 | 1082 |  | 803 |  |  |  | 1075 |
| Yeasticide |  | 268 | 216 |  | 268 |  |  |  | 269 |
| NF EN 1276 (2,1) | Bactericide |  | 219 | 177  (*E.hirae*) |  | 134 |  |  |  | 134 |
| NF EN 1650 (2,1) | Fungicide |  | 536 | 433 |  | 536 |  |  |  | 537 |
| Yeasticide |  | 219 | 177 |  | 134 |  |  |  | 215 |
| EN 13624 (2,1) | Fungicide |  |  |  |  | 618 |  |  |  |  |
| Yeasticide |  |  |  |  | 82 |  |  |  |  |
| EN 13727 (2,1) | Bactericide |  |  |  |  | 41 |  |  |  |  |
| EN 14476 - 15 min (2,1) | Virucide |  |  |  |  | n/t |  |  |  |  |
| EN 16615 - 5 min (2,2) | Bactericide |  |  |  |  | 412 |  |  |  |  |
| Yeasticide |  |  |  |  | 412 |  |  |  |  |
| EN 16615 - 15 min (2,2) | Bactericide |  |  |  |  | 82 |  |  |  |  |
| Yeasticide |  |  |  |  | 82 |  |  |  |  |

Summary of efficacy studies performed on the biocidal products included in the Meta-SPC 3, dirty conditions.

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| **Test method/ Product Name** | | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA (T +12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** |
| **Soiling conditions: Dirty** | | **Minimum effective dose of active chlorine (expressed as % of product)** | | | | | | | | |
| NF EN 13697 - 5 min - 3 g/L BSA (2,2) | Bactericide |  | 1.5 | 8  (*E.hirae*) |  | 7 |  |  |  | 7 |
| NF EN 13697 - 15 min - 3 g/L BSA (2,2) | Fungicide |  | 4 | 9 |  | 8 |  |  |  | 8 |
| Yeasticide |  | 1 | 4 |  | 3 |  |  |  | 4 |
| NF EN 1276 (2,1) | Bactericide |  | 3 | 4  (*E.hirae*) |  | 4 |  |  |  | 3 |
| NF EN 1650 (2,1) | Fungicide |  | 6 | 8 |  | 7 |  |  |  | 6 |
| Yeasticide |  | 3 | 3 |  | 3 |  |  |  | 3 |
| EN 13624 - 5 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Fungicide |  |  |  |  | 17.7 |  |  |  |  |
| Yeasticide |  |  |  |  | 7.7 |  |  |  |  |
| EN 13624 – 15 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Fungicide |  |  |  |  | 4.62 |  |  |  |  |
| Yeasticide |  |  |  |  | 0.39 |  |  |  |  |
| EN 13727 - 5 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Bactericide |  |  |  |  | 6 |  |  |  |  |
| EN 13727 - 15 min - 3 g/L BSA+3 ml/L erythrocytes (2,1) | Bactericide |  |  |  |  | 0.31 |  |  |  |  |
| EN14476 (2,1) - 5 min - 3 g/L BSA + 3 ml/L erythrocytes | Virucide |  |  |  |  | 12 |  |  |  |  |
| EN14476 (2,1) - 15 min - 3 g/L BSA + 3 ml/L erythrocytes | Virucide |  |  |  |  | 7.7 |  |  |  |  |
| EN 16615 - 5min - - 3 g/L BSA+3 ml/L erythrocytes (2,2) | Bactericide |  |  |  |  | 2.3 |  |  |  |  |
| Yeasticide |  |  |  |  | 2.3 |  |  |  |  |
| EN 16615 - 15 min - - 3 g/L BSA+3 ml/L erythrocytes (2,2) | Bactericide |  |  |  |  | 0.31 |  |  |  |  |
| Yeasticide |  |  |  |  | 0.39 |  |  |  |  |

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| **Test method/ Product Name** | | **Javel 2,6 detergence PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA** | **Javel 2,6 detergence citron PRO OXENA (T+12mois)** | **Javel 2,6 detergence eucalyptus PRO OXENA** | **Javel 2,6 PRO/GP OXENA** | **Javel 2,6 pin GP OXENA** | **Javel 2,6 eucalyptus PRO/GP OXENA** | **Javel 2,6 lavande GP OXENA** | **Javel 2,6 citron PRO/GP OXENA** |
| **Soiling conditions: Dirty** | | **Minimum effective dose of active chlorine (expressed as mg/L)** | | | | | | | | |
| NF EN 13697 - 5 min (2,2) | Bactericide |  | 402 | 1730  (*E.hirae*) |  | 1875 |  |  |  | 1808 |
| NF EN 13697 - 15 min (2,2) | Fungicide |  | 1071 | 1947 |  | 2142 |  |  |  | 2067 |
| Yeasticide |  | 268 | 865 |  | 803 |  |  |  | 1033 |
| NF EN 1276 (2,1) | Bactericide |  | 803 | 865  (*E.hirae*) |  | 1071 |  |  |  | 806 |
| NF EN 1650 (2,1) | Fungicide |  | 1607 | 1730 |  | 1875 |  |  |  | 1612 |
| Yeasticide |  | 803 | 649 |  | 803 |  |  |  | 806 |
| EN 13624 - 5 min (2,1) | Fungicide |  |  |  |  | 4738 |  |  |  |  |
| Yeasticide |  |  |  |  | 2060 |  |  |  |  |
| EN 13624 - 15 min (2,1) | Fungicide |  |  |  |  | 1236 |  |  |  |  |
| Yeasticide |  |  |  |  | 103 |  |  |  |  |
| EN 13727 - 5 min (2,1) | Bactericide |  |  |  |  | 1607 |  |  |  |  |
| EN 13727 - 15 min (2,1) | Bactericide |  |  |  |  | 82 |  |  |  |  |
| EN14476 (2,1) - 5 min | Virucide |  |  |  |  | 3214 |  |  |  |  |
| EN14476 (2,1) - 15 min | Virucide |  |  |  |  | 2060 |  |  |  |  |
| EN 16615 - 5min (2,2) | Bactericide |  |  |  |  | 618 |  |  |  |  |
| Yeasticide |  |  |  |  | 618 |  |  |  |  |
| EN 16615 - 15 min (2,2) | Bactericide |  |  |  |  | 82 |  |  |  |  |
| Yeasticide |  |  |  |  | 103 |  |  |  |  |

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| **META-SPC 3 – Javel 2.6% DETERGENCE CITRON PRO OXENA – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 détergente citron  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.6% v/v ; 0.7% v/v ; 0.8% v/v (fresh product)  0.5% v/v; 0.8% v/v; 1%v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.8% v/v (i.e. 0.0208% or 219 mg/l of a.c.) | Laboratoire Solutio 1276 propreté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | *E. hirae* | Bactericidal activity demonstrated at 0.8% v/v (i.e. 0.0168% or 177 mg/l of a.c.) | Laboratoire Solutio 1276 propreté JAVEL 2.6 DET CITRON T12  RI=1 |
| Javel 2.6 détergence citron  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v(fresh product)  1.5% v/v; 2% v/v; 2.5%v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.039% or 402 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | *E. hirae* | Bactericidal activity demonstrated at 2% v/v (i.e. 0.042% or 433 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 DET CITRON T12  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6% détergente citron  (2.6% w/w active chlorine) | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.5% v/v ; 0.8% v/v ; 1% v/v (fresh and aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at at 0.8% v/v (i.e. 0.0208% or 219 mg/l of a.c.) | Laboratoire Solutio 1650 propreté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Yeasticidal activity demonstrated at 0.8% v/v (i.e. 0.0168% or 177 mg/l of a.c.) | Laboratoire Solutio 1650 propreté JAVEL 2.6 DET CITRON T12  RI=1 |
| Javel 2.6 détergence citron  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v (fresh and aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.026% or 268 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.021% or 216 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 DET CITRON T12  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6% détergente citron  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 1% v/v ; 2% v/v ; 3% v/v (fresh and aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.052% or 536 mg/l a.c.) | Laboratoire Solutio 1650 propreté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Fungicidal activity demonstrated at 2% v/v (i.e. 0.042% or 433 mg/l a.c.) | Laboratoire Solutio 1650 propreté JAVEL 2.6 DET CITRON T12  RI=1 |
| Javel 2.6 détergence citron  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 3% v/v; 4% v/v; 5% v/v  (fresh product)  4% v/v; 5% v/v; 6% v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 4% v/v (i.e. 0.104% or 1071 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Fungicidal activity demonstrated at 5% v/v (i.e. 0.105% or 1082 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 DET CITRON T12  RI=1 |
| **META-SPC 3 – Javel 2.6% DETERGENCE CITRON PRO OXENA – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 détergente citron  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 2% v/v ; 2.5% v/v ; 3% v/v (fresh product)  3% v/v; 4% v/v; 5%v/v (aged product)  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 3% v/v (i.e. 0.0780% or 803 mg/l of a.c.) | Laboratoire Solutio 1276 saleté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | *E. hirae* | Bactericidal activity demonstrated at 4% v/v (i.e. 0.0840% or 865 mg/l of a.c.) | Laboratoire Solutio 1276 saleté JAVEL 2.6 DET CITRON T12  RI=1 |
| Javel 2.6 détergence citron  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v(fresh product)  7% v/v; 8% v/v; 9%v/v (aged product)  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.039% or 402 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | *E. hirae* | Bactericidal activity demonstrated at 8% v/v (i.e. 0.168% or 1730 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6 DET CITRON T12  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6% détergente citron  (2.6% w/w active chlorine) | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 2% v/v ; 3% v/v ; 4% v/v (fresh and aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at at 3% v/v (i.e. 0.078% or 803 mg/l of a.c.) | Laboratoire Solutio 1650 saleté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Yeasticidal activity demonstrated at 3% v/v (i.e. 0.063% or 649 mg/l of a.c.) | Laboratoire Solutio 1650 saleté JAVEL 2.6 DET CITRON T12  RI=1 |
| Javel 2.6 détergence citron  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v (fresh product)  3% v/v ; 4% v/v ; 5% v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.026% or 268 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Yeasticidal activity demonstrated at 4% v/v (i.e. 0.084% or 865 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6 DET CITRON T12  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6% détergente citron  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 5% v/v ; 6% v/v ; 7% v/v (fresh product)  7% v/v ; 8% v/v ; 9% v/v (aged product)  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 6% v/v (i.e. 0.156% or 1607 mg/l a.c.) | Laboratoire Solutio 1650 saleté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Fungicidal activity demonstrated at 8% v/v (i.e. 0.168% or 1730 mg/l a.c.) | Laboratoire Solutio 1650 saleté JAVEL 2.6 DET CITRON T12  RI=1 |
| Javel 2.6 détergence citron  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13697 Phase 2 step 2 test | Concentration tested: 3% v/v; 4% v/v; 5% v/v  (fresh product)  8% v/v; 9% v/v; 10% v/v (aged product)  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 4% v/v (i.e. 0.104% or 1071 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6 DET CITRON  RI=1 |
| Javel 2.6 détergente citron  (2.1% w/w active chlorine)  12-month aged | Fungicidal activity demonstrated at 9% v/v (i.e. 0.189% or 1947 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6 DET CITRON T12  RI=1 |
| **META-SPC 3&4 – JAVEL 2,6 PRO/GP OXENA – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.3% v/v; 0.5% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.5% v/v (i.e. 0.013% or 134 mg/l of a.c.) | Laboratoire Solutio 1276 propreté javel 2.6  RI=1 |
| PT2-disinfection of hard surfaces  MEDI-CAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 13727  Phase 2 step 1 test | Concentration in active chlorine tested:  0,001% v/v; 0,002% v/v; 0,004% v/v; 0,006% v/v; 0,008% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.004% v/v or 41 mg/l of active chlorine i.e. 0.15% v/v of product. | RE18-401-1 Solutio  RI=1 |
| PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.039% or 402 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6  RI=1 |
| PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,01% v/v; 0,02% v/v; 0,04% v/v; 0,06% v/v; 0,08% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.04% v/v or 412 mg/l of active chlorine i.e. 1.54% v/v of product. | 16615 propreté JAVEL 2.6 5min  RI=1 |
| PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,004% v/v; 0,006% v/v; 0,008% v/v; 0,01% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.008% v/v or 82 mg/l of active chlorine i.e. 0.31% v/v of product. | 16615 propreté JAVEL 2.6 15min  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 0.4% v/v ; 0.5% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.5% v/v (i.e. 0.013% or 134 mg/l of a.c.). | Laboratoire Solutio 1650 propreté Javel 2.6%  RI=1 |
| PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13624  Phase 2 step 1 test | Concentration in active chlorine tested:  0,002% v/v; 0,004% v/v; 0,006% v/v; 0,008% v/v; 0,01% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.008% v/v or 82 mg/l of active chlorine i.e. 0.31% v/v of product. | 13624 propreté JAVEL 2.6 levuricide 15 min V2  RI=1 |
| PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.026% or 268 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6  RI=1 |
| PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,01% v/v; 0,02% v/v; 0,04% v/v; 0,06% v/v; 0,08% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.04% v/v or 412 mg/l of active chlorine i.e. 1.54% v/v of product. | 16615 propreté JAVEL 2.6 5min  RI=1 |
| PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,004% v/v; 0,006% v/v; 0,008% v/v; 0,01% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.008% v/v or 82 mg/l of active chlorine i.e. 0.31% v/v of product. | 16615 propreté JAVEL 2.6 15min  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650 Phase 2 step 1 test | Concentration tested: 1.5% v/v ; 2% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.052% or 536 mg/l of a.c.) | Laboratoire Solutio 1650 propreté Javel 2.6%  RI=1 |
| PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13624  Phase 2 step 1 test | Concentration in active chlorine tested:  0,01% v/v; 0,02% v/v; 0,04% v/v; 0,06% v/v; 0,08% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 0.06% or 618 mg/l of active chlorine i.e. 2.31 % v/v of product. | RE18-398-4 Solutio  RI=2 |
| PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 2% v/v ; 3% v/v ; 4% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 3 % v/v (i.e. 0.078% or 803 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6  RI=1 |
| **META-SPC 3&4 – JAVEL 2,6 PRO/GP OXENA – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 3% v/v ; 4 % v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 4% v/v (i.e. 0.104% or 1071 mg/l of a.c.) | Laboratoire Solutio 1276 saleté javel 2.6  RI=1 |
| Bactericide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 13727  Phase 2 step 1 test | Concentration in active chlorine tested:  0,002% v/v; 0,004% v/v; 0,006% v/v; 0,008% v/v; 0,01% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.008% or 82 mg/l of active chlorine i.e. 0.31% v/v of product. | Laboratoire Solutio 13727 saleté JAVEL 2.6 15 min  RE18-400-1  RI=1 |
| Bactericide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 13727  Phase 2 step 1 test | Concentration in active chlorine tested:  0,01% v/v; 0,05% v/v; 0,156% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.156% or 1607 mg/l of active chlorine i.e. 6% v/v of product. | 13727 saleté JAVEL 2.6 5 min  RE19-838-1  RI=1 |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 3% v/v ; 4% v/v ; 5% v/v  *E. hirae* : 6% v/v ; 7% v/v ; 8% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 7% v/v (i.e. 0.182% or 1875 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6  RI=1 |
| Bactericide | PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,01% v/v; 0,02% v/v; 0,04% v/v; 0,06% v/v; 0,08% v/v;  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3 mL/L sheep erythrocytes  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.06% or 618 mg/l of active chlorine i.e. 2.3% v/v of product. | 16615 saleté JAVEL 2.6 5min  RE19-820-1  RI=1 |
| Bactericide | PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. hirae*  *S. aureus* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,006% v/v; 0,008% v/v; 0,01% v/v; 0,012% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA + 3 mL/L sheep erythrocytes  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.008% or 82 mg/l of active chlorine i.e. 0.31% v/v of product. | 16615 saleté JAVEL 2.6 15min  RE 18-395-1  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 1650  Phase 2 step 1 test | Concentration tested:  2% v/v ; 3% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 3% v/v (i.e. 0.078% or 803 mg/l of a.c.). | Laboratoire Solutio 1650 saleté JAVEL 2.6 candida réédition  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13624  Phase 2 step 1 test | Concentration tested: 3% v/v; 4% v/v; 5% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Yeasticidal activity not demonstrated | 13624 saleté JAVEL 2.6 levuricide 5 min  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13624  Phase 2 step 1 test | Concentration in active chlorine tested:  0,13% v/v; 0,20% v/v; 0,26% v/v; 0,52% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.20% or 2060 mg/l of active chlorine i.e. 7.7% v/v of product. | 13624 saleté JAVEL 2.6 levuricide 5 min V2  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13624  Phase 2 step 1 test | Concentration in active chlorine tested:  0,004% v/v; 0,006% v/v; 0,008% v/v; 0,01% v/v; 0,02% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.01% or 103 mg/l of active chlorine i.e. 0.39% v/v of product. | Laboratoire Solutio 13624 saleté JAVEL 2.6 levuricide 15 min  RE18-399-1  RI=1 |
| Yeasticide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 2% v/v ; 3% v/v ; 4% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 3% v/v (i.e. 0.078% or 803 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6  RI=1 |
| Yeasticide | PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,01% v/v; 0,02% v/v; 0,04% v/v; 0,06% v/v; 0,08% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3 mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.06% or 618 mg/l of active chlorine i.e. 2.3% v/v of product. | 16615 saleté JAVEL 2.6 5min  RE19-820-1  RI=1 |
| Yeasticide | PT2-desinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *C. albicans* | EN NF 16615  Phase 2 step 2 test | Concentration in active chlorine tested:  0,006% v/v; 0,008% v/v; 0,01% v/v; 0,012% v/v  Temperature: 20°C  Contact time: 15 min  soiling: 3 g/L BSA + 3 mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.01% or 103 mg/l of active chlorine i.e. 0.39% v/v of product. | 16615 saleté JAVEL 2.6 15min  RE 18-395-1  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650  Phase 2 step 1 test | Concentration tested:  6.5% v/v; 7% v/v; 7.5% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 7 % v/v (i.e. 0.182% or 1875 mg/l of a.c.) | Laboratoire Solutio 1650 saleté Javel 2.6 aspergillus nouvel essai  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13624  Phase 2 step 1 test | Concentration tested: 7% v/v; 10% v/v; 12% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Fungicidal activity not demonstrated. | 13624 saleté JAVEL 2.6 fongicide 5 min  RE 19-853-2  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13624  Phase 2 step 1 test | Concentration in active chlorine tested:  0,31% v/v; 0,46% v/v; 0,62% v/v; 1,2% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 0.46% or 4738 mg/l of active chlorine i.e. 17.7% v/v of product. | 13624 saleté JAVEL 2.6 fongicide 5 min V2  RE20-116-1  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13624  Phase 2 step 1 test | Concentration in active chlorine tested:  0,06% v/v; 0,08% v/v; 0,1% v/v; 0.12% v/v; 0.14% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA + 3mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 0.12% or 1236 mg/l of active chlorine i.e. 4.62% v/v of product. | Laboratoire Solutio 13624 saleté JAVEL 2.6 fongicide 15 min  RE18-399-2 Solutio  RI=1 |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 6% v/v ; 7% v/v ; 8% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 8% v/v (i.e. 0.208% or 2142 mg/l of a.c.) | Laboratoire Solutio 13697 saleté JAVEL 2.6  RI=1 |
| Virucide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL AND MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | Adenovirus type 5 | EN 14476  Phase 2 step 1 test | Concentration tested: 6%v/v ; 9%v/v ; 12%v/v  Temperature:  20°C  Contact time: 5 min  Soiling: 3 g/L BSA with 3 mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Virucidal activity demonstrated at 6 % v/v (i.e. 0.156% or 1607 mg/l of a.c.).  **No non-active concentration: test not validated.** | 14476 saleté JAVEL 2.6 5 min adenovirus  RE 19-850-4  RI = 2 |
| Murine Norovirus | Virucidal activity demonstrated at 12% v/v (i.e. 0.312% or 3214 mg/l of a.c.) | 14476 saleté JAVEL 2.6 5 min norovirus  RE 19-850-3  RI = 1 |
| Virucide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces and disinfection by soaking  NON MEDICAL AND MEDICAL SECTOR | Javel 2.6%  (2.6% w/w active chlorine) | Adenovirus type 5 | EN 14476  Phase 2 step 1 test | Concentration in active chlorine tested:  Adenovirus : 0,02% v/v; 0,04% v/v; 0,06% v/v; 0.08% v/v; 0.1% v/v  Norovirus: 0,1% v/v; 0,2% v/v; 0,3% v/v; 0.4% v/v; 0.5% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA + 3 mL/L sheep erythrocytes  Criteria: ≥4 log reduction | Virucidal activity demonstrated at 0.04% or 412 mg/l of active chlorine i.e. 1.54% v/v of product. | 14476 saleté JAVEL 2.6 15 min adenovirus  RE 19-823-1  RI=1 |
| Murine Norovirus | Virucidal activity demonstrated at 0.2% or 2060 mg/l of active chlorine 7.7% v/v of product. | 14476 saleté JAVEL 2.6 15 min Murine Norovirus  RE 18-393-3  RI=1 |
| **META-SPC 3&4 – Javel 2.6 CITRON – CLEAN CONDITIONS** | | | | | | | |
| Bactericide | PT2-desinfection of hard surfaces  PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 citron  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 0.3% v/v; 0.4% v/v; 0.5% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 0.5% v/v (i.e. 0.013% or 134 mg/l of a.c.). | Laboratoire Solutio 1276 propreté JAVEL 2.6 CITRON  RI = 1 |
| EN NF 13697  Phase 2 step 2 test | Concentration tested: 0.5% v/v; 1% v/v; 1.5% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 1.5% v/v (i.e. 0.039% or 403 mg/l of a.c.). | Laboratoire Solutio 13697 propreté JAVEL 2.6 CITRON  RI = 1 |
| Yeasticide | PT2-desinfection of hard surfaces  PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 citron  (2.6% w/w active chlorine) | *C. albicans* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 0.5% v/v; 0.8% v/v; 1% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 0.8% v/v (i.e. 0.0208% or 215 mg/l of a.c.) | Laboratoire Solutio 1650 propreté JAVEL 2.6 CITRON  RI = 1 |
| EN NF 13697  Phase 2 step 2 test | Concentration tested: 0.5% v/v ; 1% v/v ; 1.5% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 1% v/v (i.e. 0.026% or 269 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 CITRON  RI = 1 |
| Fungicide | PT2-desinfection of hard surfaces  PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 citron  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 1% v/v; 2% v/v; 3% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 2% v/v (i.e. 0.052% or 537 mg/l of a.c.) | Laboratoire Solutio 1650 propreté JAVEL 2.6 CITRON  RI = 1 |
| EN NF 13697  Phase 2 step 2 test | Concentration tested: 2% v/v; 3% v/v; 4% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 0.3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 4% v/v (i.e. 0.104% or 1075 mg/l of a.c.) | Laboratoire Solutio 13697 propreté JAVEL 2.6 CITRON  RI = 1 |
| **META-SPC 3&4 – Javel 2.6 CITRON – DIRTY CONDITIONS** | | | | | | | |
| Bactericide | PT2-desinfection of hard surfaces  PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 citron  (2.6% w/w active chlorine) | *P. aeruginosa*  *E. coli*  *E. hirae*  *S. aureus* | EN NF 1276 Phase 2 step 1 test | Concentration tested: 2% v/v; 2.5% v/v; 3% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | Bactericidal activity demonstrated at 3% v/v (i.e. 0.078% or 806 mg/l of a.c.). | Laboratoire Solutio 1276 saleté JAVEL 2.6 CITRON  RI = 1 |
| Javel 2.6 citron  (2.5% w/w active chlorine) | EN NF 13697  Phase 2 step 2 test | Concentration tested:  E. hirae, S. aureus : 5% v/v; 6% v/v; 7% v/v  P. aeruginosa, E. coli : 3% v/v; 4% v/v; 5% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 7% v/v (i.e. 0.175% or 1808 mg/l of a.c.). | Laboratoire Solutio 13697 saleté JAVEL 2.6 CITRON  RI = 1 |
| Yeasticide | PT2-desinfection of hard surfaces  PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 citron  (2.6% w/w active chlorine) | *C. albicans* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 2% v/v ; 3% v/v; 4% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Yeasticidal activity demonstrated at 3% v/v (i.e. 0.078% or 806 mg/l of a.c.). | Laboratoire Solutio 1650 saleté JAVEL 2.6 CITRON  RI = 1 |
| Javel 2.6 citron  (2.5% w/w active chlorine) | EN NF 13697  Phase 2 step 2 test | Concentration tested: 3% v/v ; 4% v/v ; 5% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Yeasticidal activity demonstrated at 4% v/v (i.e. 0.100% or 1033 mg/l of a.c.). | Laboratoire Solutio 13697 saleté JAVEL 2.6 CITRON  RI = 1 |
| Fungicide | PT2-desinfection of hard surfaces  PT4-desinfection of hard surfaces and disinfection by soaking  NON MEDICAL SECTOR | Javel 2.6 citron  (2.6% w/w active chlorine) | *A. brasiliensis* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 5% v/v; 6% v/v; 7% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 6% v/v (i.e. 0.156% or 1612 mg/l of a.c.). | Laboratoire Solutio 1650 saleté JAVEL 2.6 CITRON  RI = 1 |
| Javel 2.6 citron  (2.5% w/w active chlorine) | EN NF 13697  Phase 2 step 2 test | Concentration tested: 6% v/v; 7% v/v; 8% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥3 log reduction | Fungicidal activity demonstrated at 8% v/v (i.e. 0.200% or 2067 mg/l of a.c.). | Laboratoire Solutio 13697 saleté JAVEL 2.6 CITRON  RI = 1 |

**Meta-SPC 3 – Bleach 2.6% professional:**

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| **Conclusion on the efficacy for the meta SPC 3** |
| For meta SPC 3 tests were performed with formulations JAVEL 2.6, JAVEL 2.6 CITRON and JAVEL 2.6 DÉTERGENCE CITRON. The application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted for each product (phase 1 test versus phase 2 test, fresh product versus aged product). Therefore for some uses, activities or target organisms claimed, the application rate validated are higher than claimed and then restrictions in the use conditions are applied.  Moreover, when comparing tests results expressed in mg/L active chlorine obtained for all test formulations when tested fresh and aged, it can be concluded that, in some tests, results obtained are quite different under the same test conditions. Thus, efficacy is different between formulations of the same META-SPC, thus variations of co-formulants have an impact on efficacy. Therefore, efficacy of the whole META-SPC 3 are only validated for the uses for wich a common data set is available between the tested products JAVEL 2.6 PRO OXENA (fresh and aged), JAVEL 2.6 DETERGENCE CITRON PRO OXENA (fresh product only) and JAVEL 2.6 CITRON PRO OXENA (fresh product only). The worst case is taken into account to validate the active chlorine efficient dose of Meta-SPC 3.   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Product** | **PT** | **Field of use envisaged** | **Target organisms** | **Soiling conditions** | **Contact time** | **Application rate claimed in**  **% of product**  **(*mg/L of active chlorine*)** | **Effective concentration**  **in % of product**  **(*mg/L of active chlorine in the test product*)** | | **Validated application rate in % of product**  **(*mg/L of active chlorine*)** | **Conclusion on the use** | | Fresh | 12-month aged | | JAVEL 2.6 PRO OXENA (2.6% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Non medical sector | Mandatory:  Bacteria | Clean | 5 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 7% v/v  (*1875 mg/L*) |  | 8% v/v  (*2142 mg/L*)  Without mechanical action | Validated | | Optional:  Yeasts | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*268 mg/L*) |  | 1% v/v  (*268 mg/L*)  Without mechanical action | Validated | | Optional:  Yeasts | Dirty | 15 min | 7.7% v/v  (*2000 mg/L*) | 3% v/v  (*803 mg/L*) |  | 7.7% v/v  (2060 *mg/L*)  Without mechanical action | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 8% v/v  (*2142 mg/L*) |  | 17.7% v/v  (*4738 mg/L*) | Validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated for limited spectrum virucidal activity only | | 2 | # 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector | Mandatory:  Bacteria | Clean | 5 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 7% v/v  (*1875 mg/L*) |  | 8% v/v  (*2142 mg/L*)  Without mechanical action | Validated | | Optional:  Yeasts | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*268 mg/L*) |  | 1% v/v  (*268 mg/L*)  Without mechanical action | Validated | | Optional:  Yeasts | Dirty | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (1071 *mg/L*)  Without mechanical action | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 8% v/v  (*2142 mg/L*) |  | 8% v/v  (*20142 mg/L*) | Validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated for limited spectrum virucidal activity only | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 5 min | 8% v/v  (2080 *mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | % v/v  (*2142 mg/L*)  With mechanical action | Not validated | | Optional:  Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Optional:  Fungal spore | Dirty | 5 min | 17.7% v/v  (*4600 mg/L*) | 17.7% v/v  (*4738 mg/L*) |  | 17.7% v/v  (*4738 mg/L*)  With mechanical action | Not validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | Limited spectrum virucidal activity  8% v/v  (*2142 mg/L*) | Not validated | | 2 | # 3 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 8% v/v  (*2142 mg/L*)  With mechanical action | Validated | | Optional:  Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Optional:  Fungal spore | Dirty | 5 min | 17.7% v/v  (*4600 mg/L*) | 17.7% v/v  (*4738 mg/L*) |  | 17.7% v/v  (*4738 mg/L*)  With mechanical action | Validated | | Optional:  Virus | Dirty | 5 min | 12% v/v  (*3120 mg/L*) | 12% v/v  (*3214 mg/L*) |  | Limited spectrum virucidal activity  12% v/v  (*3214 mg/L*) | Validated for limited spectrum virucidal activity only | | 2 and 4 | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  Medical sector and non-medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Clean  Dirty |  |  |  |  |  | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring  # 7 - Disinfection of equipment/materials by immersion/soaking  Food and feed area  Non-medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7% v/v  (*1875 mg/L*) |  | 8% v/v  (*2142 mg/L*)  Without mechanical action | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 8% v/v  (*2142 mg/L*) |  | 17.7% v/v  (*4738 mg/L*) | Validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated | | 4 | # 8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  Food and feed area | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 0.5% v/v  (*134 mg/L*) |  | 1.5% v/v  (*402 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (2060 *mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 2% v/v  (53*6 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 5 min | 17.7% v/v  (*4600 mg/L*) | 17.7% v/v  (*4738 mg/L*) |  | 17.7% v/v  (*4738 mg/L*) | Validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated | | JAVEL 2.6 CITRON PRO OXENA (2.6% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Non medical sector | Mandatory:  Bacteria | Clean | 5 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Mandatory:  Bacteria | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 7% v/v  (*1808 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Yeasts | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*269 mg/L*) |  | 1% v/v  (*269 mg/L*) | Validated | | Yeasts | Dirty | 15 min | 7.7 v/v  (*2000 mg/L*) | 4% v/v  (*1033 mg/L*) |  | 7.7% v/v  (*2069 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 8% v/v  (*2067 mg/L*) |  | 17.7% v/v  (*4755 mg/L*) | Validated | | Optional:  Virus | Dirty |  |  |  |  |  | Not validated | | 2 | # 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector | Mandatory:  Bacteria | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Mandatory:  Bacteria | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7% v/v  (*1808 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Yeasts | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*269 mg/L*) |  | 1% v/v  (*269 mg/L*) | Validated | | Yeasts | Dirty | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1033 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 8% v/v  (*2067 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Optional:  Virus | Dirty |  |  |  |  |  | Not validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector  # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector  # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Dirty |  |  |  |  |  | Not validated | | 2 and 4 | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  Non medical and medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Clean  Dirty |  |  |  |  |  | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring  # 7 - Disinfection of equipment/materials by immersion/soaking  Food and feed area  Non-medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7% v/v  (*1808 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 8% v/v  (*2067 mg/L*) |  | 17.7% v/v  (*4755 mg/L*) | Validated | | Optional:  Virus | Dirty |  |  |  |  |  | Not validated | | # 8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  Food and feed area | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 0.8% v/v  (*215 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 3% v/v  (*806 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 2% v/v  (*537 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 6% v/v  (*1612 mg/L*) |  | 17.7% v/v  (*4755 mg/L*) | Validated | | Optional:  Virus | Dirty |  |  |  |  |  | Not validated | | JAVEL 2.6 DETERGENCE CITRON PRO OXENA (2.6% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Non medical sector | Mandatory:  Bacteria | Clean | 5 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) | 2% v/v  (*433 mg/L*) | 2% v/v  (*547 mg/L*) | Validated | | Mandatory:  Bacteria | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 1.5% v/v  (*402 mg/L*) | 8% v/v  (*1730 mg/L*) | 8% v/v  (*2188 mg/L*) | Validated | | Yeasts | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*268 mg/L*) | 1% v/v  (*216 mg/L*) | 1% v/v  (*274 mg/L*) | Validated | | Yeasts | Dirty | 15 min | 7.7% v/v  (*2000 mg/L*) | 1% v/v  (*268 mg/L*) | 4% v/v  (*865 mg/L*) | 7.7% v/v  (*2106 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1071 mg/L*) | 5% v/v  (*1082 mg/L*) | 5% v/v  (*1368 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 4% v/v  (*1071 mg/L*) | 9% v/v  (*1947 mg/L*) | 17.7% v/v  (*4842 mg/L*) | Validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) |  |  |  | Not validated | | 2 | # 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector | Mandatory:  Bacteria | Clean | 5 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) | 2% v/v  (*433 mg/L*) | 2% v/v  (*547 mg/L*) | Validated | | Mandatory:  Bacteria | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 1.5% v/v  (*402 mg/L*) | 8% v/v  (*1730 mg/L*) | 8% v/v  (*2188 mg/L*) | Validated | | Yeasts | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*268 mg/L*) | 1% v/v  (*216 mg/L*) | 1% v/v  (*274 mg/L*) | Validated | | Yeasts | Dirty | 15 min | 4% v/v  (*1040 mg/L*) | 1% v/v  (*268 mg/L*) | 4% v/v  (*865 mg/L*) | 4% v/v  (1094 *mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1071 mg/L*) | 5% v/v  (*1082 mg/L*) | 5% v/v  (*1368 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 4% v/v  (*1071 mg/L*) | 9% v/v  (*1947 mg/L*) | 9% v/v  (*2462 mg/L*) | Validated | | Optional:  Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) |  |  |  | Not validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector  # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) | 2% v/v  (*433 mg/L*) | 2% v/v  (*547 mg/L*) | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1071 mg/L*) | 5% v/v  (*1082 mg/L*) | 5% v/v  (*1368 mg/L*) | Validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector  # 3 - Disinfection of hard surfaces by Spraying, wiping, pouring, mopping or scrubbing  Medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Dirty |  |  |  |  |  | Not validated | | 2 and 4 | # 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  Non medical and medical sector  # 7 - Disinfection of equipment/materials by immersion/soaking  Medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Clean  Dirty |  |  |  |  |  | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring  # 7 - Disinfection of equipment/materials by immersion/soaking  Food and feed area  Non-medical sector | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) | 2% v/v  (*433 mg/L*) | 2% v/v  (*547 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 1.5% v/v  (*402 mg/L*) | 8% v/v  (*1730 mg/L*) | 8% v/v  (*2188 mg/L*)  Without mechanical action | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1071 mg/L*) | 5% v/v  (*1082 mg/L*) | 5% v/v  (*1368 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 4% v/v  (*1071 mg/L*) | 9% v/v  (*1947 mg/L*) | 17.7% v/v  (*4842 mg/L*) | Validated | | Optional:  Virus | Dirty |  |  |  |  |  | Not validated | | # 8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  Food and feed area | Mandatory:  Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 0.8% v/v  (*219 mg/L*) | 0.8% v/v  (*177 mg/L*) | 1.5% v/v  (*410 mg/L*)  Without mechanical action | Validated | | Mandatory:  Bacteria  Yeasts | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 3% v/v  (*803 mg/L*) | 4% v/v  (*865 mg/L*) | 8% v/v  (*2188 mg/L*)  Without mechanical action | Validated | | Optional:  Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 2% v/v  (*536 mg/L*) | 2% v/v  (*433 mg/L*) | 4% v/v  (*1094 mg/L*) | Validated | | Optional:  Fungal spores | Dirty | 15 min | 17.7% v/v  (*4600 mg/L*) | 6% v/v  (*1607 mg/L*) | 8% v/v  (*1730 mg/L*) | 17.7% v/v  (*4842 mg/L*) | Validated | | Optional:  Virus | Dirty |  |  |  |  |  | Not validated |   Regarding use in healthcare, for fungicidal activity in dirty conditions, no phase 2 step 2 test with specific soiling conditions (3 g/L BAS + 3 g/L sheep erythrocytes) has been submitted. Thus, fungicidal efficacy in dirty conditions without mechanical action in healthcare is not demonstrated for use #1.  Regarding use #3 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing in healthcare, efficacy is validated with mechanical action only. Indeed, only phase 2 step 2 tests with specific soiling conditions with mechanical action has been submitted.  Regarding use # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring without mechanical action in healthcare, for efficacy in dirty conditions, only phase 2 step 2 tests with specific soiling conditions with mechanical action has been submitted. Thus, efficacy in dirty conditions without mechanical action is not demonstrated for use #1 in healthcare.  Regarding virucidal activity, laboratory suspension tests were performed with viruses (EN 14476, 20°C, 5 and 15 min contact time, dirty conditions) only with JAVEL 2.6. However, as Poliovirus has not been tested for PT2 uses, a full virucidal activity is not demonstrated but only a limited spectrum virucidal activity. Moreover according to the TAB, limited spectrum virucidal activity can only be validated for professional users.  Regarding PT2 use #1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) (non medical sector and medical sector), PT2 uses # 2 and 3 disinfection of hard surfaces, PT4 uses #5 disinfection of hard surfaces, for scrubbing/mopping/wipping mode of applications, phase 2 step 2 tests without mechanical action in clean conditions (0.3 g/L BAS) and with mechanical action in dirty conditions (3 g/L BAS + 3 mL erythrocytes) have been submitted for the product JAVEL 2.6. However, no phase 2 step 2 test without mechanical action in dirty conditions for the healthcare area has been submitted. Thus, for the product JAVEL 2.6, bactericidal and yeasticidal activities for uses #1 and use #3 in dirty conditions in healthcare is only validated with mechanical action.  As representative products are not all tested for use in healthcare and for uses where mechanical action is involved, virucidal efficacy, efficacy against bacteria, fungi and yeasts for uses in healthcare (use #1 and use #3) in dirty conditions, and efficacy against bacteria and yeasts for surface treatments implying mechanical action, is not demonstrated for both JAVEL 2.6 CITRON and JAVEL 2.6 DÉTERGENCE CITRON.  Moreover, for these products, a mechanical action is claimed for use #2, #3 and #5, but no tests with mechanical action have been submitted. eCA consider that wiping/mopping in such cases is considered as a way of distributing the product without any real mechanical action, then according to the TAB for these exceptions, EN 13697 is considered applicable. Efficacy is then demonstrated when product is applied onto surfaces without mechanical action by spraying/wiping/mopping/pouring followed after the contact time by a mechanical action such as scrubbing/wiping/mopping if needed. A specific instruction for use is added in the SPC.  Regarding applications in milk and dairy production and milking parlour systems in use #8, no specific soiling condition (10 g/L skimmed milk) has been tested. Efficacy for these uses is not validated in dirty conditions, disinfection has to be performed only in clean conditions. A specific instruction for use has to be added in the SPC.  Regarding use #6 “disinfection of equipment/materials by automatic spraying in closed systems (tunnels)”, in absence of further details provided by the applicant, eCA considered it equivalent to “Disinfection in dishwashing machines and crate washers”. However for this use, for all test organisms phase 2 step 1 tests, phase 2 step 2 tests and phase 3 tests are required. In the absence of phase 3 tests, efficacy for this use is not demonstrated.  Conclusion regarding the validation of the efficacy of Meta-SPC 3:  As efficacy can differ between tested formulations of META-SPC 3, thus variations of co-formulants have no neutral action on efficacy. Therefore, efficacy of the whole META-SPC 3 is only validated for the uses for wich a common data set is available between the tested products JAVEL 2.6 Detergence citron PRO OXENA (fresh and aged) JAVEL 2.6 PRO OXENA and JAVEL 2.6 CITRON PRO OXENA (fresh product only). The worst case (highest effective active chlorine concentration covering all tested products) is taken into account to validate the active chlorine efficient dose.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **PT** | **Field of use envisaged** | **user** | **Target organisms** | **Soiling conditions** | **Contact time** | **Worst case application rate in mg/L of active chlorine to be validated for the meta-SPC** | | | | | **2** | **# 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring   Non Medical sector** |  | Bacteria | Clean | 5 min | 403 | | Bacteria | Dirty | 5 min | 2149 | | Yeast | Clean | 15 min | 274 | | Yeast | Dirty | 15 min | 2106 | | Fungal spore | Clean | 15 min | 1368 | | Fungal spore | Dirty | 15 min | 4842 | | Virus | Dirty | 15 min | Not validated | | **# 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring   Medical sector** |  | Bacteria Yeasts | Clean | 15 min | 547 | | Bacteria Yeasts | Dirty | 15 min | Not validated | | Fungal spore | Clean | 15 min | 1368 | | Fungal spore | Dirty | 5 min | Not validated | | Virus | Dirty | 15 min | Not validated | | **# 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector** |  | bacteria | clean | 5 | 547 | | bacteria | dirty | 5 | 2188 | | yeast | clean | 15 | 274 | | yeast | dirty | 15 | 1094 | | fungal spore | clean | 15 | 1368 | | fungal spore | dirty | 15 | 2462 | | virus | dirty | 15 | Not validated | | **# 3 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing   Medical sector** |  | Bacteria Yeasts | Clean | 15 | 547 | | Bacteria Yeasts | Dirty | 15 min | Not validated | | Fungal spore | Clean | 15 min | 1368 | | Fungal spore | Dirty | 5 min | Not validated | | Virus | Dirty | 5 min | Not validated | | **# 7- Disinfection of equipment/materials by immersion/soaking    Non medical sector** |  | bacteria | clean | 5 | 547 | | bacteria | dirty | 5 | 2188 | | yeast | clean | 15 | 274 | | yeast | dirty | 15 | 2106 | | fungal spore | clean | 15 | 1368 | | fungal spore | dirty | 15 | 4842 | | virus | dirty | 15 | Not validated | | **2 et 4** | **# 6 - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  Medical sector and non-medical sector** |  | Bacteria Yeasts Fungal spores Viruses | Clean Dirty |  | Not validated | | **4** | **# 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring** |  | Bacteria Yeasts | Clean | 15 min | 547 | | Bacteria Yeasts | Dirty | 5 min | 2188 | | Fungal spore | Clean | 15 min | 1368 | | Fungal spore | Dirty | 15 min | 4842 | | Virus | Dirty | 15 min | Not validated | | **# 7 - Disinfection of equipment/materials by immersion/soaking Food and feed area Non-medical sector** |  | Bacteria Yeasts | Clean | 15 min | 547 | | Bacteria Yeasts | Dirty | 15 min | 2188 | | Fungal spore | Clean | 15 min | 1368 | | Fungal spore | Dirty | 15 min | 4842 | | Virus | Dirty | 15 min | Not validated | | **# 8 - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  Food and feed area** |  | Bacteria Yeasts | Clean | 15 min | 410 | | Bacteria Yeasts | Dirty | 5 min | 2188 | | Fungal spore | Clean | 15 min | 1094 | | Fungal spore | Dirty | 5 min | 4842 | | Virus | Dirty | 15 min | Not validated | |

In the SPC, if needed, mandatory and optional target organisms have been grouped with regard to the worst case application rate and contact time.

**4) Meta-SPC 4 – Bleach 2.6% non-professional**

PT2 – Hard surfaces in medical and non-medical sector: uses #1 and 2

PT4 – Hard surfaces in Food and Feed area: use # 5

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| **Conclusion on the efficacy for the meta SPC 4** |
| For META SPC 3 tests were performed with formulations JAVEL 2.6 and JAVEL 2.6 CITRON, the same as for META-SPC 3. Phase 2 step 1 and/or phase 2 step 2 tests were performed with bacteria, fungal spore, yeasts and viruses (EN 1276, 13727, 1650, 13624, 14476, 13697, 16615, 20°C, 5 and/or 15 min contact time, clean and/or dirty conditions).  The application rates are validated for each use and activity claimed, taken into account the worst case of efficacy studies submitted for each product (phase 1 test versus phase 2 test, fresh product versus aged product).   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Product** | **PT** | **Field of use envisaged** | **Target organisms** | **Soiling conditions** | **Contact time** | **Application rate claimed in**  **% of product**  **(*mg/L of active chlorine*)** | **Effective concentration**  **in % of product**  **(*mg/L of active chlorine in the test product*)** | | **Validated application rate in % of product**  **(*mg/L of active chlorine*)** | **Conclusion on the use** | | Fresh | 12-month aged | | JAVEL 2.6 GP OXENA (2.6% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector  # 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector | Bacteria | Clean | 5 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Bacteria | Dirty | 5 min | 7% v/v  (*1820 mg/L*) | 7% v/v  (*1875 mg/L*) |  | 7% v/v  (*1875 mg/L*)  Without mechanical action | Validated | | Yeast | Clean | 15 min | 1% v/v  (*260 mg/L*) | 1% v/v  (*268 mg/L*) |  | 1% v/v  (*268 mg/L*)  Without mechanical action | Validated | | Yeast | Dirty | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (1071 *mg/L*)  Without mechanical action | Validated | | Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 8% v/v  (*2142 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated | | Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | Limited spectrum virucidal activity  8% v/v  (*2142 mg/L*) | Not validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector | Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Bacteria  Yeasts | Dirty | 15 min | 7% v/v  (*1820 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 7.7% v/v  (*2060 mg/L*)  With mechanical action | Not validated | | Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Fungal spore | Dirty | 5 min | 8% v/v  (*2080 mg/L*) | 17.7% v/v  (*4738 mg/L*) |  | 17.7% v/v  (*4738 mg/L*)  With mechanical action | Not validated | | Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | Limited spectrum virucidal activity  8% v/v  (*2142 mg/L*) | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring | Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*402 mg/L*) |  | 1.5% v/v  (*402 mg/L*)  Without mechanical action | Validated | | Bacteria  Yeasts | Dirty | 15 min | 7% v/v  (*1820 mg/L*) | 7% v/v  (*1875 mg/L*) |  | 7% v/v  (*1875 mg/L*)  Without mechanical action | Validated | | Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 3% v/v  (*803 mg/L*) |  | 4% v/v  (*1071 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 8% v/v  (*2142 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated | | Virus | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 7.7% v/v  (*2060 mg/L*) |  | 8% v/v  (*2142 mg/L*) | Validated | | JAVEL 2.6 CITRON GP OXENA (2.6% active chlorine) | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non medical sector | Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 7% v/v  (*1820 mg/L*) | 7% v/v  (*1808 mg/L*) |  | 7% v/v  (*1881 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 8% v/v  (*2067 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Virus | Dirty |  |  |  |  |  | Not validated | | 2 | # 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector | Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 7% v/v  (*1820 mg/L*) | 7% v/v  (*1808 mg/L*) |  | 7% v/v  (*1881 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 8% v/v  (*2080 mg/L*) | 8% v/v  (*2067 mg/L*) |  | 8% v/v  (*2149 mg/L*) | Validated | | Virus | Dirty |  |  |  |  |  | Not validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector | Bacteria  Yeasts | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Fungal spores | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector | Bacteria  Yeasts  Fungal spores  Viruses | Dirty |  |  |  |  |  | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring | Bacteria  Yeast | Clean | 15 min | 1.5% v/v  (*390 mg/L*) | 1.5% v/v  (*403 mg/L*) |  | 1.5% v/v  (*403 mg/L*) | Validated | | Bacteria  Yeasts | Dirty | 15 min | 7% v/v  (*1820 mg/L*) | 7% v/v  (*1808 mg/L*) |  | 7% v/v  (*1881 mg/L*) | Validated | | Fungal spore | Clean | 15 min | 4% v/v  (*1040 mg/L*) | 4% v/v  (*1075 mg/L*) |  | 4% v/v  (*1075 mg/L*) | Validated | | Fungal spore | Dirty | 15 min | 8% v/v  (*2080 mg/L* | 8% v/v  (*2067 mg/L*) |  | 8% v/v  (*2149 mg/L* | Validated | | Virus | Dirty |  |  |  |  |  | Not validated |   Regarding use in healthcare, for fungicidal activity in dirty conditions, no phase 2 step 2 test with specific soiling conditions has been submitted. Thus, fungicidal efficacy in dirty conditions without in healthcare is not demonstrated.  Regarding use # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring without mechanical action in healthcare, for efficacy in dirty conditions, only phase 2 step 2 tests with specific soiling conditions with mechanical action has been submitted. Thus, efficacy in dirty conditions without mechanical action is not demonstrated for use #1 in healthcare.  Regarding virucidal activity, laboratory suspension tests were performed with viruses (EN 14476, 20°C, 5 and 15 min contact time, dirty conditions) with JAVEL 2.6. However, as Poliovirus has not been tested for PT2 uses, no full virucidal activity is demonstrated and a limited spectrum virucidal activity cannot be validated for PT2 as products of this meta-SPC are intended to be used by non-professionnal users.  Phase 2 step 2 tests in clean conditions (0.3 g/L BAS) and dirty conditions (3 g/L BAS + 3 mL erythrocytes) with mechanical action have been submitted. However, no phase 2 step 2 tests without mechanical action in dirty conditions for the healthcare domain has been submitted. Thus, bactericidal and yeasticidal activities for use #1 in dirty conditions without mechanical action in healthcare is not demonstrated.  When comparing tests results expressed in mg/L active chlorine obtained for both tested formulations, it can be concluded that in some cases results obtained are different under same test conditions. Thus, read across between the formulations of meta spc 4 cannot be accepted. Thus, for JAVEL 2.6 CITRON, virucidal efficacy, efficacy against bacteria, fungi and yeasts for uses in healthcare (use #1 and use #3) in dirty conditions, and efficacy against bacteria and yeasts for surface treatments implying mechanical action, is not demonstrated.  Conclusion regarding the validation of the efficacy of Meta-SPC 4:  As efficacy can differ between formulations of META-SPC 4, thus variations of co-formulants have no neutral action on efficacy. Therefore, efficacy of the whole META-SPC 4 is only validated for the uses for wich a common data set is available between the tested products JAVEL 2.6 PRO OXENA and JAVEL 2.6 CITRON PRO OXENA (fresh product only). The worst case (highest effective active chlorine concentration covering all tested products) is taken into account to validate the active chlorine efficient dose.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **PT** | **Field of use envisaged** | **user** | **Target organisms** | **Soiling conditions** | **Contact time** | **Worst case application rate in mg/L of active chlorine to be validated for the meta-SPC** | | **2** | **# 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Non Medical sector** |  | Bacteria | Clean | 5 min | 403 | | Bacteria | Dirty | 5 min | 1881 | | Yeast | Clean | 15 min | 269 | | Yeast | Dirty | 15 min | 1075 | | Fungal spore | Clean | 15 min | 1075 | | Fungal spore | Dirty | 15 min | 2149 | | Virus | Dirty | 15 min | Not validated | | **# 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring  Medical sector** |  | Bacteria Yeasts | Clean | 15 min | 403 | | Bacteria Yeasts | Dirty | 15 min | Not validated | | Fungal spore | Clean | 15 min | 1075 | | Fungal spore | Dirty | 5 min | Not validated | | Virus | Dirty | 15 min | Not validated | | **# 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector** |  | bacteria | clean | 5 | 403 | | bacteria | dirty | 5 | 1881 | | yeast | clean | 15 | 269 | | yeast | dirty | 15 | 1075 | | fungal spore | clean | 15 | 1075 | | fungal spore | dirty | 15 | 2149 | | virus | dirty | 15 | Not validated | | **4** | **# 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring** |  | Bacteria Yeasts | Clean | 15 min | 403 | | Bacteria Yeasts | Dirty | 15 min | 1881 | | Fungal spore | Clean | 15 min | 1075 | | Fungal spore | Dirty | 15 min | 2149 | | Virus | Dirty | 15 min | Not validated |   In the SPC, if needed, mandatory and optional target organisms have been grouped with regard to the worst case application rate and contact time. |

**5) Meta-SPC 6 – Bleach 4.8% non-professional:**

PT2 – Hard surfaces in medical and non-medical sector: ues #1 and 2

PT4 – Hard surfaces in Food and Feed area: use #5

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| **Conclusion on the efficacy for the meta SPC 6** |
| The composition of the products included in this meta-SPC are with or without perfume and surfactant. These products are intended to be systematically diluted to obtain a solution at a concentration of 2.6% of active chlorine that should be diluted another time at the efficient dilution. Efficacy for meta-SPC 6 is based on that of meta SPC 3.   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **PT** | **Field of use envisaged** | **user** | **Target organisms** | **Soiling conditions** | **Contact time** | **Application rate claimed in**  **% of product**  **(*mg/L of active chlorine*)** | **Validated application rate in % of product**  **(*mg/L of active chlorine*)**  **JAVEL 2.6 PRO OXENA (2.6% active chlorine)** | **Validated application rate in % of product**  **(*mg/L of active chlorine*)**  **JAVEL 2.6 citron PRO OXENA (2.6% active chlorine)** | **Worst case application rate in mg/L of active chlorine to be validated for the meta-SPC** | | 2 | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring   Non Medical sector | NP | Bacteria | Clean | 5 min | 0,8% v/v  (*390 mg/L*) | 0,8% v/v  (*413 mg/L*)  Without mechanical action | 0,8% v/v  (413 mg/L) | 413 | | Bacteria | Dirty | 5 min | 3,8% v/v  (1820 mg/L) | 3,8% v/v  (1961 mg/L)  Without mechanical action | 3,8% v/v  (1961 mg/L)  Without mechanical action | 1961 | | Yeast | Clean | 15 min | 0,5% v/v  (*260 mg/L*) | 0,52  (*268 mg/L*)  Without mechanical action | 0,52%  (269 mg/L) | 269 | | Yeast | Dirty | 15 min | 2,2% v/v  (104*0 mg/L*) | 2,2% v/v  (1135 *mg/L*)  Without mechanical action | 2,20%  (1135 mg/L) | 1135 | | Fungal spore | Clean | 15 min | 2,2% v/v  (*1040 mg/L*) | 2,2% v/v  (1135 *mg/L*) | 2,2% v/v  (*1135 mg/L*) | 1075 | | Fungal spore | Dirty | 15 min | 4,4% v/v  (2080 *mg/L*) | 4,4% v/v  (2270 *mg/L*) | 4,4% v/v  (2270 *mg/L*) | 2270 | | Virus | Dirty | 15 min | 4,4% v/v  (*2080 mg/L*) | Not validated | Not validated | Not validated | | # 1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring   Medical sector | NP | Bacteria Yeasts | Clean | 15 min | 0,8% v/v (390 mg/L) | 0,8% v/v  (*413 mg/L*)  Without mechanical action | 0,8% v/v (413 mg/L) Without mechanical action | 413 | | Bacteria Yeasts | Dirty | 15 min | 3,8% v/v  (*1820 mg/L*) | Not validated | Not validated | Not validated | | Fungal spore | Clean | 15 min | 2,2% v/v (1040 mg/L) | 2,2% v/v  (1135 *mg/L*) | 2,2% v/v (1135 mg/L) | 1135 | | Fungal spore | Dirty | 15 min | 4,4% v/v  (2080 *mg/L*) | Not validated | Not validated | Not validated | | Virus | Dirty | 15 min | 4,4% v/v  (*2080 mg/L*) | Not validated | Not validated | Not validated | | # 2 - Disinfection of hard surfaces by spraying, wiping, pouring, mopping or scrubbing  Non medical sector | NP | bacteria | clean | 5 | 0,8% v/v (390 mg/L) | 0,8% v/v (413 mg/L) without mechanical action | 0,8% v/v (413 mg/L) without mechanical action | 413 | | bacteria | dirty | 5 | 3,8% v/v (1820 mg/L) | 3,8% v/v (1961 mg/L) without mechanical action | 3,8% v/v (1961 mg/L) without mechanical action | 1961 | | yeast | clean | 15 | 0,5% v/v (260 mg/L) | 0,52% v/v (268 mg/L) without mechanical action | 0,52% v/v (269 mg/L) without mechanical action | 269 | | yeast | dirty | 15 | 2,2% v/v (1040 mg/L) | 2,2% v/v (1135 mg/L) without mechanical action | 2,2% v/v (1135 mg/L) without mechanical action | 1075 | | fungal spore | clean | 15 | 2,2% v/v (1040 mg/L) | 2,2% v/v (1135 mg/L) | 2,2% v/v (1135 mg/L) | 1135 | | fungal spore | dirty | 15 | 4,4% v/v (2080 mg/L) | 4,4% v/v (2270 mg/L) without mechanical action | 4,4% v/v (2270 mg/L) without mechanical action | 2270 | | virus | dirty | 15 | 4,4% v/v (2080 mg/L) | Limited spectrum 4,4% v/v (2270 mg/L) | Not validated | Not validated | | 4 | # 5 - Disinfection of hard surfaces in contact with food by spraying, wiping, mopping, scrubbing or pouring | NP | Bacteria Yeasts | Clean | 15 min | 0,8% v/v (390 mg/L) | 0,8% v/v (413 mg/L) without mechanical action | 0,8% v/v (413 mg/L) without mechanical action | 413 | | | | Bacteria Yeasts | Dirty | 15 min | 3,8% v/v (1820 mg/L) | 3,8% v/v (1961 mg/L) without mechanical action | 3,8% v/v (1961 mg/L) without mechanical action | 1961 | | | | Fungal spore | Clean | 15 min | 2,2% v/v (1040 mg/L) | 2,2% v/v (1135 mg/L) | 2,2% v/v (1135 mg/L) | 1135 | | | Fungal spore | Dirty | 15 min | 4,4% v/v (2080 mg/L) | 4,4% v/v (2270 mg/L) | 4,4% (2270 mg/L) | 2270 | | | Virus | Dirty | 15 min | 4,4% v/v (2080 mg/L) | 4,4% v/v (2270 mg/L) | Not validated | Not validated | |   In the SPC, if needed, mandatory and optional target organisms have been grouped with regard to the worst case application rate and contact time. |

**6) Meta-SPC 7 – Thick Bleach professional**

PT2 – Hard surfaces in medical and non-medical sector

PT4 – Hard surfaces in Food and Feed area

PT2 #1 - Disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) (Non medical sector and Medical sector)

PT2 #2 - Disinfection of hard surfaces, used other than in healthcare

PT4 #5 - Disinfection of hard surfaces

META-SPC 7 contains products to be diluted or to be used as ready-to-use products containing active chlorine at 2.3 % w/w, and no variations of coformulants. Efficacy studies have been performed with the representative product GEL JAVEL PRO OXENA (Chlorigel). Taking into account that no variations occur in the META-SPC7, the efficacy results of the representative product cover the whole META-SPC7 claims.

Phase 2 step 1 and/or phase 2 step 2 tests were performed on bacteria and fungal spores (EN 1276, 1650, 13697, 20°C, 5 and/or 15 min contact time, dirty conditions) with fresh product.

It has to be noted that no studies on yeasts have been submitted.

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| --- | --- | --- | --- |
| **Test method/ Product Name** | | **Gel javel PRO OXENA** | |
| **Soiling conditions: Dirty** | | **Minimum effective dose expressed as % of product** | **Minimum effective dose of active chlorine (expressed as mg/L)** |
| NF EN 13697 - 5 min - 3 g/L BSA (2,2) | Bactericide | Not validated | Not validated |
| NF EN 13697 - 15 min - 3 g/L BSA (2,2) | Fungicide | 7 | 1771 |
| Yeasticide | n/t | n/t |
| NF EN 1276 (2,1) | Bactericide | Not validated | Not validated |
| NF EN 1650 (2,1) | Fungicide | Not validated | Not validated |
| Yeasticide | n/t | n/t |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces  NON MEDICAL SECTOR | CLORIGEL  (2.3% w/w active chlorine) | *P. aeruginosa*  *E. hirae* | EN NF 1276  Phase 2 step 1 test | Concentration tested: 2% v/v; 3% v/v  Temperature: 20°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥5 log reduction | TEST NOT VALIDATED  C < 0,5Nv0 for *E. hirae*  *Only two target organisms have been tested (S.aureus and E.coli are missing)* | Laboratoire Solutio 1276 saleté GEL JAVEL  RI = 3 |
| *E. hirae* | EN NF 13697  Phase 2 step 2 test | Concentration tested: 6% v/v ; 7% v/v ; 8% v/v  Temperature: 18-25°C  Contact time: 5 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Bactericidal activity demonstrated at 7 % v/v (i.e. 0.161% v/v or 1771 mg/l of a.c.)  Only *E. hirae* has been tested. | Laboratoire Solutio 13697 saleté GEL JAVEL  RI = 3 (missing target organisms) |
| Fungicide | PT2-disinfection of hard surfaces  PT4-disinfection of hard surfaces  NON MEDICAL SECTOR | CLORIGEL  (2.3% w/w active chlorine) | *A. brasiliensis* | EN NF 1650  Phase 2 step 1 test | Concentration tested: 5% v/v ; 6% v/v ; 7% v/v  Temperature: 20°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 6 % v/v (i.e. 0.138% v/v or 1518 mg/l of a.c.)  TEST NOT VALIDATED  => N < 1,5e7 | Laboratoire Solutio 1650 saleté GEL JAVEL  RI=3 |
| EN NF 13697  Phase 2 step 2 test | Concentration tested: 6% v/v ; 7% v/v ; 8% v/v  Temperature: 18-25°C  Contact time: 15 min  Soiling: 3 g/L BSA  Criteria: ≥4 log reduction | Fungicidal activity demonstrated at 7% v/v (i.e. 0.161% v/v or 1771 mg/l of a.c.) | Laboratoire Solutio 13697 saleté GEL JAVEL  RI = 1 |

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| **Conclusion on the efficacy for the meta SPC 7** |
| According to the Guidance on the BPR Vol.II part B/C, for PT2:   * For disinfection of sanitary installations (e.g. toilet bowls, drains, sink, etc.) by pouring in non-medical sector (# 1) and for disinfection of hard surfaces other than in healthcare by spraying, wiping, pouring, mopping or scrubbing (# 2): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.   According to the Guidance on the BPR Vol.II part B/C, for PT4:   * For disinfection of hard surfaces (#5): phase 2 step 1 and phase 2 step 2 tests on bacteria and yeasts are basic requirements; fungal spores are optional organisms for wich phase 2 step 1 and phase 2 step 2 tests are needed.   With regard to the submitted tests, only EN 13697 study on fungal spores is validated. Furthermore, no tests have been performed on yeasts. Efficacy for the claimed uses and thus for products of the meta-SPC 7 is not demonstrated. |

**7) Meta-SPC 5 – Anti-lichen professional:**

PT2 #4 - Anti-lichen and anti-algae treatment of hard surfaces (such as wall, floor, roof, etc.)

META-SPC 5 contains ready-to-use products containing active chlorine at 6 % w/w and variations of perfumes, surfactant and sequestrant. Efficacy studies have been performed with the representative product EXTIMUM without perfume (other trade name: Klin façade, or Anti-lichen, please refer to the SPC or glossary provided summarising all the trade name of this formulation).

Laboratory tests (according to OECD 201 standard adapted) on algae, and semi-field tests were performed on algae and lichens, with fresh product. Data from the field are also provided by the applicant to support the use in field conditions (“extimum\_field\_2014” document provided in the Iuclid dossier).

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC5** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Algicide | PT2-Anti-lichen and anti-algae treatment of hard surfaces | Anti-lichen | *Chlorella vulgaris* | Internal method adapted from OCDE 201  Quantitative suspension test  Determination of a percentage of inhibition. | Determination of growth by fluorescence and macroscopic observation.  Product concentration tested: 1 %; 10 %; 100 % of ready-to-use formulation.  Inoculation at 1.6 x 106 cells / ml  3 replicates  Assessment at: 0, 3 6 and 24h  Test temperature not mentionned | Fluorescence:  100% growth inhibition demonstrated at 1%, 10% and 100% of ready-to-use formulation, from 3h up to 24h exposure.  Macroscopic observation:  No green coloration after 24h exposure to 10% and 100% of ready-to-use formulation.  Decrease of intensity of the green coloration after 24h for the 1% concentration.  Growth is observed in the control. | Rovaltain Research Company, RAPPORT FINAL Etude hors BPL N°RRCO-000400\_01, Anti-lichen, Test d’efficacité vis-à-vis de *Chlorella vulgaris*  RI = 2 |
| Algicide  Lichenicide | PT2-Anti-lichen and anti-algae treatment of hard surfaces | EXTINUM (Anti-lichen)  6,2% active chlorine | Chlorophyta :  *Chlorella vulgaris,*  *Pseudokirchneriella subcapitata*  *Tetraselmis suecica* | Semi-field study  Visual assessment by considering macroscopic changes compared to the control group, in particular changes in the coloration of algae and / or lichens on the supports.  Size of inoculum unknown | Laboratory test on 6 tiles (porous support) and 6 PVC gutters (non-porous support) were inoculated with algae.  Concentrations tested 1L/10 m² et 3L/10 m² of ready-to-use formulation.  Control: water treatment.  Observation at 0, 2, 4, 24 and 48h.  Criteria: macroscopic changes compared to the control group.  48h after treatment, treated and control surfaces were moistened regurlarly during 15 days in order to evaluate the regrowth capacity of the algae. | Algicidal activity (no green coloration) demonstrated at 1L/10m² and 3L/10m² of ready-to-use formulation after 24h.  No regrowth is observed during 15 days.  The control became green. | Rovaltain Research Company, RAPPORT FINAL Etude hors BPL N°RRCO-000597\_01  RI = 2 |
| Chlorophyta & Lichens | Laboratory test on tiles (porous support) and PVC gutters (non-porous support) coming from the field and already covered with algae and lichens.  Concentrations tested 1L/10 m² et 3L/10 m² of ready-to-use formulation.  Control: water treatment.  Observation at 0, 2, 4, 24 and 48h.  Criteria: macroscopic changes compared to the control group.  48h after treatment, treated and control surfaces were moistened regurlarly during 15 days in order to evaluate the regrowth capacity of the algae. | No differences between treated and non-treated surfaces.  Efficacy is not demonstrated. |
| Algicide  Lichenicide | PT2-Anti-lichen and anti-algae treatment of hard surfaces | klin façade (= EXTINUM) | Chlorophyta &  Lichens | Pictures taken during field treatments (facade, low walls, ground). | Concentration 0.3l/m² of ready-to-use product.  High pressure application  Criteria: visual observation before and after treatment. | No study report.  No determination of the target organisms on the surfaces to be treated.  No control in parallel therefore the added physical effect of the high pressure cannot be estimated  no | Professional applicators  Supportive data |

|  |
| --- |
| **Conclusion on the efficacy for the meta SPC 5** |
| Based on the adapted OECD 201 study, Extimum product (called “anti-lichen” in this study) shows growth inhibition of the green algae *Chlorella vulgaris* after 24 hours exposure at the concentration of 10%.  Regarding the semi-field trial carry out with Extimun product it can be concluded that, for algae inoculated artificially on both porous and non-porous surfaces in 24 hours at both 0.1 and 0.3 l/m², there is a difference between treated and non treated tiles (no green coloration for the treated tiles) but inoculum seemed to be low as surfaces were poorly green before treatment (the size of the inoculum is unknown). In this same study, the laboratory test on surfaces taken from the field and covered by algae and lichens did not demonstrated any differences between treated and non-treated surfaces or even between before and after treatment.  Efficacy against lichens and algae on hard surfaces (roofs, floors, hard surfaces) is also highlighted by the “extimum\_field\_2014” document provided in the Iuclid dossier, for which “Extimum” is called “Klin façade”. Even if the pictures demonstrated a clear difference before and after treatment at the application rate of 0.3 L/m², it is to be noted that the provided document that contains only pictures is not robust enough alone to support the claim. Moreover the effect alone of high pressure is not assessed with a control.  Use of PT2 #4 - Anti-lichen and anti-algae treatment of hard surfaces (such as wall, floor, roof, etc.) is not validated for META-SPC 5. |

#### **Occurrence of resistance and resistance management**

Although different species of target organisms vary in their sensitivity to active chlorine, the development of resistance is not expected due to the unspecific mode of action. The acquisition of resistance of biocidal products is in principle most feasible if the biocidal product operates against a specific cellular target and where the biocidal product is stable such that low, sub-lethal concentrations of the biocide can persist to which viable organisms remain continuously exposed over long time periods. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003, Doc. No.: 392-070 and Submission to SCENIHR, February 2008, Doc. No.: 392-069)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite the use for almost a century in purifying drinking water, where very low (sub ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed.

Due to its reactive nature and unspecific mode of action, no management strategies have been developed since an acquired resistance to active chlorine is not expected. Some temporary adaptation giving modestly reduced susceptibility is sometimes observed in organisms exposed continuously at low concentrations (e.g. in water pipes through formation of biofilms) but this is readily managed e.g. by control / removal of the biofilm. Sabyet al, (1999, Appl Environ Microbiol. 65(12): 5600–5603, Doc. No.: 392-068) reported that oxidative stress, independent of the nature of the oxidant, lead to a development of resistance of bacteria probably by GSH homeostasis. Industries using hypochlorite at low concentrations already routinely manage their operations to cope with such temporarily reduced susceptibility. [from Assessment Report of Active chlorine released from sodium hypochlorite (January 2017), section 2.1.2.]

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### **Known limitations**

Sodium hypochlorite aqueous solutions could be corrosive to metals. Common metals should never be used for the storage or handling of such solutions.

#### **Evaluation of the label claims**

The uses assessed in this dossier belong to the Product Type 2 and the Product Type 4.

The products are used by industrial, professional and non-professional users.

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

#### **Relevant information if the product is intended to be authorised for use with other biocidal product(s)**

Any biocidal product included in the BPF is not intended to be used in combination with other biocidal products.

### Risk assessment for human health

The Assessment Reports for Active Chlorine released from sodium hypochlorite (PT2 and PT4, Italy, January 2017) state that sodium hypochlorite dissociates in water to form the sodium cation (Na+) and hypochlorite anion (ClO-), which is characterised by its well-known irritating/corrosive effects. Hypochlorite is in equilibrium of hypochlorous acid (HClO) and chlorine (Cl2). The remaining sodium cation is a physiologically essential element and required in intermediary metabolism. During BPC TOX-WGIII-2016, the members agreed that human health effects are primarily due to the local mode of action of sodium hypochlorite and potential systemic effects are secondary to its direct irritating reactivity.

With the exception of in vitro skin corrosion tests conducted with Afise Javel 4.8%, covering products of meta-SPC 6, and Javel Détergente Citron 2.6%, covering products of meta-SPC 3 and 4, no data product are available. Classification is addressed based on available information on the active substance and co-formulants, according to the guidance of the CLP Regulation (EC No 1272/2008).

Sodium chlorate is a relevant impurity of the active substance sodium hypochlorite and can also be formed during the storage of the product.

For the majority of Meta-SPC, the long-term stability test (please refer to the Physical, Chemical and technical part) shows a content of sodium chlorate at final time (expressed as % of active chlorine content) above the specification limit for sodium chlorate, which is of maximum 5.4% w/w of available chlorine.

As chlorate presents an acute toxicity by oral route (harmonised classification Acute Tox. 4 – H302), it is not covered by the toxicity of the active substance. Therefore, the content of sodium chlorate at final time of the stability study will be taken into account for the classification of the different meta-SPC.

Moreover the presence of chlorate should be taken into account to perform a systemic risk assessment. However, in the absence of harmonisation of the reference values for chlorate, no risk assessment can be performed. This should be postponed to the renewal of the active substance.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

***Meta-SPC 1, 2, 5 and 7***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Corrosive to skin |
| Justification for the value/conclusion | Taking into account the extreme pH of the formulations (>11.5), products from meta SPC 1, 2, 5 and 7 are considered corrosive to the skin. |
| Classification of the product according to CLP | The meta-SPC 1, 2, 5 and 7 are classified as Skin Corrosive 1; H314, according to the CLP criteria. |

***Meta-SPC 3, 4 and 6***

| **Summary table of in vitro studies on skin corrosion/irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| *In vitro Membrane Barrier Test Method for skin corrosion,*  OECD Guideline 435 (July 2015),  GLP compliance,  Reliability level: 1 | Test item : Afise Javel (4.8% of available chlorine, qsp water)  Tested neat (without dilution)  500µl – four replicates  Positive control: sodium hydroxide 50%, sulphuric acid 10%  Negativ control: citric acid 10% | The CORROSITEX™ Assay was used | The test was performed following 3 steps.  The first step was conducted to verify the applicability of the method, which was confirmed by a color change (from yellow to purple) of the tested sample.  The 2nd step assigned a Category 2 to the product after a color change (from uncolored to slight grey) of the test item during the confirmation test (no color change during the first step of the Categorisation step).  During the last step, there is no disruption of the membrane by the test item after 1h.  According to the OECD guideline and GHS criteria, the product is not considered corrosive to skin. | There were no deviations and the assay acceptance criteria were met. | Faccioli, 2014,  Report N° S-2014-01732 AMi |
| In Vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test,    OCDE Guideline 431 (November 2004),  GLP compliance,  Reliability level: 1 | Test item : Javel Detergence Citron (2.6% of availaible chlorine) (Batch 18001249)  Tested neat (without dilution) | The SkinEthic TM RHE test was used | The measured cellular viabilities were of 103.47% after 3 min of exposure and 58.67% after 60 min of exposure.  Considering the obtained results, the test substance is considered as not corrosive based on the GHS criteria. | There were no amendments and/or deviation from the guideline.  Negative (Sterile ddH2O) and positive (KOH, 8N) controls tested in parallel confirmed the validity and the reproductibility of the assay | Manera, 2018  Final report n° n°18.637766.0001 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Irritating to skin |
| Justification for the value/conclusion | The *in vitro* skin corrosion (CORROSITEX™ and RHE) assays performed respectively on the products Afise Javel (4.8% avCl) and Javel Detergence Citron (2.6% avCl) confirmed that the products are not corrosive to skin.  The active substance content in these products is between 1 and 5% in the mixture. Therefore, a classification as Category 2 Skin Irritant is required for these products, according to the specific concentration limit of the active substance and CLP Regulation.  The two tested products Afise Javel and Javel Detergence Citron are respectively representative of the products of meta-SPC 6 and meta-SPC 3 and 4. The results can therefore be extrapolated to the other products from meta-SPC 3, 4 and 6. |
| Classification of the product according to CLP | The meta-SPC 3, 4 and 6 are classified as Skin Irritant 2; H315, according to the CLP criteria. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Causes eye damage |
| Justification for the value/conclusion | The pH is above 11.5 for all the products of the biocidal product family and the content of active substance exceeds the GCL of 1% in all the products. Therefore, the products should be considered as corrosive Skin Corr 1 – H314 and should be classified Category 1 Eye Damaging, according to the CLP Regulation. |
| Classification of the product according to CLP and DSD | All meta-SPC are classified as Eye Dam 1; H318, according to the CLP criteria. |

***Respiratory tract irritation***

***Meta-SPC 1, 2, 5 and 7***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The active substance is not classified as a respiratory tract irritant. The PT2 and PT4 Assessment Reports for Active chlorine released from sodium hypochlorite (January 2017) note that sodium hypochlorite aerosols may be irritant to the respiratory tract.  According to the Guidance on the Application of the CLP Criteria, a classification for corrosivity is considered to implicitly cover the potential to cause respiratory tract irritation. Additional classification for Respiratory tract irritation is not required.  However, as products of meta-SPC 1, 2, 5 and 7 are classified Corrosive to skin (H314) and claimed for spraying application, the mention EUH071: corrosive to the respiratory tract is required and a qualitative risk assessment is performed. |
| Classification of the product according to CLP and DSD | No classification required but the mention EUH071: corrosive to the respiratory tract is required for meta-SPC 1, 2, 5 and 7. |

***Meta-SPC 3, 4 and 6***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The active substance is not classified as a respiratory tract irritant. The PT2 and PT4 Assessment Reports for Active chlorine released from sodium hypochlorite (January 2017) note that sodium hypochlorite aerosols may be irritant to the respiratory tract.  According to the Guidance on the Application of the CLP Criteria, a classification for corrosivity is considered to implicitly cover the potential to cause respiratory tract irritation. Additional classification for Respiratory tract irritation is not required. The mention EUH071 is also not required as the products of meta-SPC 3, 4 and 6 are not classified as Skin corrosive (H314). |
| Classification of the product according to CLP and DSD | No classification required. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensiting to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal products in the BPF “OXENA FAMILY” and their content in the products, no classification for skin sensitizing properties is required. |
| Classification of the product according to CLP and DSD | No classification required |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory tract |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal products in the BPF “OXENA FAMILY”. None of the components is classified for respiratory sensitizing properties. |
| Classification of the product according to CLP and DSD | No classification required |

***Acute toxicity***

No data on acute toxicity by oral, dermal and inhalation route is available for the biocidal products in the BPF “OXENA family”. The classification of the products has been performed according to the calculation rules laid down in the CLP regulation.

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | No acutely toxic via the oral route |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal products in the BPF “OXENA family”. For details on the calculations, please refer to the confidential PAR. |
| Classification of the product according to CLP and DSD | No classification required |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via the inhalation route. |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal products in the BPF “OXENA family”. For details on the calculations, please refer to the confidential PAR. |
| Classification of the product according to CLP and DSD | No classification required |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via the dermal route. |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal products in the BPF “OXENA family”. None of the components is classified for acute dermal toxicity properties. |
| Classification of the product according to CLP and DSD | No classification required |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Sodium hypochlorite |
| Value(s) | Not relevant |
| Justification for the selected value(s) | Local mode of action: skin corrosion/irritation and oxidization at the site of first contact |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of Regulation (EC) No. 528/2012 (BPR), point 8.6 “Dermal absorption” |
| Justification | With respect to the biocidal products in “OXENA family”, dermal absorption is not considered relevant. Toxicity of the biocidal products is characterised by the active substance releaser sodium hypochlorite, which acts by a local mode of action due to direct chemical reactivity. In the absence of clear systemic effects, dermal absorption values were not deemed necessary; a default value of 100 % was set in the “Active chlorine released from sodium hypochlorite Assessment Report” (Sodium hypochlorite in PT2-5, Italy, 2017). |

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

The products in the BPF “OXENA family” contain one substance of concern:

- Sodium hydroxide for meta-SPC 1, 5 and 7

Please refer to the Confidential Annex for further information.

***Available toxicological data relating to a mixture***

Not relevant

***Other***

#### Exposure assessment and Risks characterisation

The biocidal product family “OXENA Family” is composed of 7 meta-SPC that are each composed of several biocidal products:

* Meta-SPC 1– Food industry
* Meta-SPC 2 – Bleach 9.6 - 12.5% professional
* Meta-SPC 3 – Bleach 2.6% professional
* Meta-SPC 4 – Bleach 2.6% non-professional
* Meta-SPC 5 – Anti-lichen professional
* Meta-SPC 6 – Bleach 4.8% non-professional
* Meta-SPC 7 – Thick Bleach professional

These products are part of the Main Group 1: Disinfectants, PT2: Disinfectants and algeacides not intended for direct application to humans or animals, and PT4: Food and feed area.

Each of them are expected to be used in one or several of these 9 different uses:

* Use 1: Disinfection of sanitary installations (non medical and medical sectors) (e.g. toilet bowls, drains, sink, etc.) by pouring
* Use 2: Disinfection of hard surfaces (non medical sector) by spraying, wiping, pouring, mopping or scrubbing
* Use 3: Disinfection of hard surfaces (medical sector) by spraying, wiping, pouring, mopping or scrubbing
* Use 4: Anti-lichen and anti-algae treatment of hard surfaces by spraying
* Use 5: Disinfection of hard surfaces in contact with food by spraying, wiping, pouring, mopping or scrubbing
* Use 6: Disinfection of equipment/materials by spraying
* Use 7: Disinfection of equipment/materials by immersion/soaking
* Use 8: Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP)
* Use 9: Disinfection of inner surfaces in veterinary water systems

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Meta-SPC | **User** | **Use 1** | **Use 2** | **Use 3** | **Use 4** | **Use 5** | **Use 6** | **Use 7** | **Use 8** | **Use 9** |
| 1 | Pro / Ind |  |  |  |  | X | X |  | X | X |
| 2 | Pro | X | X | X |  | X | X | X | X | X |
| 3 | Pro | X | X | X |  | X | X | X | X |  |
| 4 | Non Pro | X | X |  |  | X |  |  |  |  |
| 5 | Pro |  |  |  | X |  |  |  |  |  |
| 6 | Non pro | X | X |  |  | X |  |  |  |  |
| 7 | Pro | X | X |  |  | X |  |  |  |  |

Based on the composition of the different products of each meta-SPC, the worst-case content of sodium hypochlorite (as available chlorine) for each meta-SPC is:

* 6.3% w/w for meta-SPC 1
* 12.5% w/w for meta-SPC 2
* 2.6% w/w for meta-SPC 3
* 2.6% w/w for meta-SPC 4
* 6% w/w for meta-SPC 5
* 4.8% w/w for meta-SPC 6
* 2.2% w/w for meta-SPC 7

The content of active chlorine in the dilution for each meta-SPC and each use is based on the maximum values validated by efficiency tests (see Efficacy section). If no value has been validated, the content of active chlorine in the dilution is calculated according to the claimed doses of the applicant.

The active substance releaser Sodium hypochlorite is characterised by primarily local effects (i.e corrosion or irritation due to direct chemical reactivity). According to the Assessment Report (Italy, 2017) any systemic effects observed in toxicity studies were considered as secondary effects. Consequently, a local risk assessment was performed for the products of Oxena BPF.

Exposure assessment is performed for Na(OCl)2 as available chlorine (avCl) according to the assessment report of the active substance Sodium hypochlorite.

In water, sodium hypochlorite (Na(OCl)2) hydrolyzes to hypochlorous acid (HClO). Furthermore, hypochlorous acid participates in the following equilibrium with chlorine (Cl2)

HClO + H3O+ + Cl─ ↔ Cl2 + 2H2O

The ratio of Cl2/HClO/ClO─ is pH and temperature dependent. At pH values > 10, the hypochlorite anion (ClO-) is the predominant species and only exposure to aerosols of Na(OCl)2 (as avCl) is considered relevant. The minor fraction of volatile hypochlorous acid (HClO) is considered negligible.

The product of the family are to be diluted in water or ready-to use products with a pH higher than 10. Therefore only exposure to aerosols of Na(OCl)2 (as avCl) is considered relevant. The minor fraction of volatile hypochlorous acid (HClO) is considered negligible. No exposure to vapour should be considered as it is assumed to be negligible.

Considering this:

* A quantitative local risk assessment is performed for inhalation exposure to Na(OCl)2 (as avCl) aerosols;
* A qualitative local risk assessment is performed for dermal exposure to Na(OCl)2 (as avCl) when the product is classified.

No oral exposure is assessed based on the claimed uses.

Secondary exposure upon dermal contact with dry treated surfaces is considered to be non-relevant. The 2017 eCA (Italy) assessment reports (ARs) for active chlorine released from sodium hypochlorite concluded that secondary dermal exposure to dry treated surfaces or equipment may be considered non-relevant. Due to the high reactivity of chlorine species such as Na(OCl)2, residues on surfaces degrade very rapidly. Decomposition to physiological sodium and chloride ions takes place which are not expected to arise any health risk.

Secondary exposure to NaOCl upon dermal contact with wet treated surfaces during contact time is considered relevant for assessment for bystander and general public for surface disinfection. Inhalation exposure after application of NaOCl is also considered relevant for the assessment of secondary exposure.

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | Yes | Yes | Yes | No | Yes | Yes | na |
| Dermal | Yes | Yes | Yes | No | No | Yes | na |
| Oral | No | No | No | No | No | Yes | Yes |

***List of exposure scenarios***

**Summary table: exposure scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: exposure scenarios for professionals/industrials** | | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Use 1** | ***Disinfection of sanitary installations (toilet bowls, drains, sinks, etc.) (Meta-SPC 2, 3 and 7)*** | | |
| **Primary exposure** | | | |
| **Scenario 1** | ***Disinfection of sanitary installations by pouring*** | **Professionals** |
| Task 1.1 | *Mixing and loading* | Professionals |
| Task 1.2 | *Application by pouring* | Professionals |
| **Uses 2, 3 and 5** | ***Disinfection of hard surfaces (medical and non medical sector) (Meta-SPC 1, 2, 3 and 7)*** | | |
| **Primary exposure** | | | |
| **Scenario 2** | ***Disinfection of hard surfaces by spraying*** | **Professionals / industrials** |
| Task 2.1 | *Mixing and loading* | Professionals / industrials |
| Task 2.2 | *Application by spraying with a trigger spray* | Professionals / industrials |
| Task 2.3 | *Application by spraying with a compression sprayer (1-3 bar)* | Professionals / industrials |
| Task 2.4 | *Application by spraying with a Venturi disinfection plant* | Professionals / industrials |
| Task 2.5 | *Post-application – Rinsing of product with a cloth (use 5 only)* | Professionals / industrials |
| Task 2.6 | *Post-application – Rinsing of product with a compression sprayer (use 5 only)* | Professionals / industrials |
| Task 2.7 | *Post-application – Rinsing of product with a Venturi disinfection plant (use 5 only)* | Professionals / industrials |
| Task 2.8 | *Post-application – Cleaning equipment (compression sprayer)* | Professionals / industrials |
| **Scenario 3** | ***Disinfection of hard surfaces by mopping / wipping / scrubbing*** | **Professionals / industrials** |
| Task 3.1 | *Mixing and loading* | Professionals / industrials |
| Task 3.2 | *Application by mopping/wiping/scrubbing* | Professionals / industrials |
| Task 3.3 | *Post-application – Rinsing of product with a cloth (use 5 only)* | Professionals / industrials |
| Task 3.4 | *Post-application – Rinsing of product with a mop (use 5 only)* | Professionals / industrials |
| **Scenario 4** | ***Disinfection of hard surfaces by pouring*** | **Professionals / industrials** |
| Task 4.1 | *Mixing and loading* | Professionals / industrials |
| Task 4.2 | *Application by pouring* | Professionals / industrials |
| Task 4.3 | *Post-application – Rinsing of product with a cloth (use 5 only)* | Professionals / industrials |
| **Secondary exposure** | | | |
| **Scenario 5** | ***Exposure of a bystander*** | **Bystander** |
| **Scenario 6** | ***Contact with wet treated surface*** | **Bystander** |
| **Use 4** | ***Anti-lichen and anti-algae treatment of hard surfaces (Meta-SPC 5)*** | | |
| **Primary exposure** | | | |
| **Scenario 7** | ***Anti-lichen and anti-algae treatment of hard surfaces by spraying*** | **Professionals** |
| Task 7.1 | *Application by spraying with a compression sprayer (1-3 bar)* | Professionals |
| Task 7.2 | *Post-application – Rinsing with water* | Professionals |
| Task 7.3 | *Post-application – Cleaning equipment (compression sprayer)* | Professionals |
| **Secondary exposure (professionals)** | | | |
| **Scenario 8** | ***Exposure of a bystander*** | **Bystander** |
| **Use 6** | ***Disinfection of equipment/materials by spraying (Meta-SPC 1, 2 and 3)*** | | |
| **Primary exposure** | | | |
| **Scenario 9** | ***Disinfection of equipment/materials by automated spraying*** | **Professionals / industrials** |
| Task 9.1 | *Mixing and loading* | Professionals / industrials |
| Task 9.2 | *Application by automatic spraying* | Professionals / industrials |
| Task 9.3 | *Post-application – Rinsing* | Professionals / industrials |
| Task 9.4 | *Post-application – Handling of treated equipment/materials* | Professionals / industrials |
| Task 9.5 | *Post-application – Cleaning or maintenance of tunnel* | Professionals / industrials |
| **Secondary exposure** | | | |
| **Use 7** | ***Disinfection of equipement/materials by immersion/soaking (Meta-SPC 2 and 3)*** | | |
| **Primary exposure** | | | |
| **Scenario 10** | ***Disinfection of equipment/materials by dipping*** | **Professionals / industrials** |
| Task 10.1 | *Mixing and loading* | Professionals / industrials |
| Task 10.2 | *Application by dipping in an immersion bath* | Professionals / industrials |
| Task 10.3 | *Post-application – Rinsing with water* | Professionals / industrials |
| **Secondary exposure** | | | |
| **Uses 8 and 9** | ***Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) and Disinfection of inner surfaces in veterinary water systems (Meta SPC 1, 2 and 3)*** | | |
| **Primary exposure** | | | |
| **Scenario 11** | ***Disinfection by cleaning-in-place (CIP) and automatic circulation into veterinary water systems*** | **Professionals / industrials** |
| Task 11.1 | *Mixing and loading* | Professionals / industrials |
| Task 11.2 | *Application: Disinfection by cleaning-in-place (CIP) and automatic circulation into veterinary water systems* | Professionals / industrials |
| Task 11.3 | *Post-application – Rinsing* | Professionals / industrials |
| Task 11.4 | *Post-application – Repair or cleaning of dosing pump* | Professionals / industrials |
| Task 11.5 | *Post-application – Repair or cleaning of circuit system* | Professionals / industrials |
| **Secondary exposure** | | | |

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios for non professionals** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Use 1** | ***Disinfection of sanitary installations (toilet bowls, drains, sinks, etc.) (Meta SPC 4 and 6)*** | |
| **Primary exposure** | | |
| **Scenario 12** | ***Disinfection of sanitary installations by pouring*** | **Non-professionals** |
| Task 12.1 | *Mixing and loading* | Non-professionals |
| Task 12.2 | *Application by pouring* | Non-professionals |
| **Uses 2 and 5** | ***Disinfection of hard surfaces (Meta SPC 4 and 6)*** | |
| **Primary exposure** | | |
| **Scenario 13** | ***Disinfection of hard surfaces by spraying*** | **Non-professionals** |
| Task 13.1 | *Mixing and loading* | Non-professionals |
| Task 13.2 | *Application by spraying with a trigger spray* | Non-professionals |
| Task 13.3 | *Post-application – Rinsing of product with a cloth* | Non-professionals |
| **Scenario 14** | ***Disinfection of hard surfaces by mopping/wiping/scrubbing*** | **Non-professionals** |
| Task 14.1 | *Mixing and loading* | Non-professionals |
| Task 14.2 | *Application by mopping/wiping/scrubbing* | Non-professionals |
| Task 14.3 | *Post-application – Rinsing of product with a cloth / mop* | Non-professionals |
| **Scenario 15** | ***Disinfection of hard surfaces by pouring*** | **Non-professionals** |
| Task 15.1 | *Mixing and loading* | Non-professionals |
| Task 15.2 | *Application by pouring* | Non-professionals |
| Task 15.3 | *Post-application – Rinsing of product with a cloth* | Non-professionals |
| **Secondary exposure – General public** | | |
| **Scenario 16** | ***Exposure of a bystander*** | **Bystander** |
| **Scenario 17** | ***Dermal exposure of the general public to the wet product and oral exposure due to hand-to-mouth transfer*** | **General public** |

Reference values to be used in Risk Characterisation

|  |  |  |
| --- | --- | --- |
| **Substance** | **Exposure route** | **Reference value** |
| Sodium hypochlorite 1 | Oral | NOAECoral = 0.1 % avCl |
| Dermal | NOAECdermal = 1.0 % avCl |
| Inhalation | AECinhal = 0.5 mg/m³ avCl |
| Chlorate 1 | Oral | ARfD = 0.036 mg/kg bw/d |
| Oral | ADI = 0.003 mg/kg bw/d |

1 according to the Assessment report for Active chlorine released from sodium hypochlorite, Italy, January 2017

***Industrial exposure and******Professional exposure***

**Use 1: Disinfection of sanitary installations (toilet bowls, drains, sinks, etc.) – PT 2 (Meta-SPC 2, 3 and 7)**

**Primary exposure**

**Scenario 1: Disinfection of sanitary installations by pouring**

The concentrated products of meta-SPC 2 and 3 are diluted into water prior to their application. The product of meta-SPC 7 is ready-to-use, therefore no mixing and loading is needed.

The maximal dose for each meta-SPC is:

* 6053 mg/L as available chlorine for meta-SPC 2
* 4842 mg/L as available chlorine for meta-SPC 3
* 70 ml of product Gel javel (RTU) for meta-SPC 7

The product is diluted in water according to the claimed doses of the applicant (except for products of meta-SPC 7), then manually poured into sanitary installations, such as toilet bowls, drains, sinks.

The classification of the dilutions (see confidential PAR for detailed explanations) /RTU product is reported in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta-SPC** | **2** | **3** | **7** |
| Use 1 | 0.6053% | 0.4842% | 2.2% |
| NC | H318 | H314 H318 |

Exposure during the cleaning of equipment (bucket) is covered by the exposure during application.

Only dermal exposure is expected during the different tasks.

A qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

*Task [1.1] – Mixing and loading*

| **Description of Task [1.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 2 and 3 are diluted into water at the claimed dose. The dilution step either is done manually if the packaging is less than 20L, or (semi) automatically if the packaging is more than 20L.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of all the meta-SPC concerned, inhalation of vapours of HClO is negligible. Exposure to aerosol is also considered negligeable for manual loading due to small quantities and for (semi) automated loading as no exposure is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [1.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [1.1] | 1/ No PPE | negligeable |

*Task [1.2] – Application by pouring*

| **Description of Task [1.2] – Application by pouring** |
| --- |
| The diluted product for meta-SPC 2 and 3 and the RTU product for meta-SPC 7 is manually poured in sanitary installations (toilet bowls, drains, sinks, etc.).  During the application, only dermal exposure to either the diluted or concentrated product is expected.  Exposure by inhalation is considered negligeable as no vapour is expected. As pH > 10 for the dilution or RTU for all meta-SPC, inhalation of vapours of HClO is negligible.  For RTU, no dilution is expected and according to the applicant, 70 ml of concentrated product is applied.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [1.2]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [1.2] | 1/ No PPE | negligeable |

**Combined exposure**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

**Risk characterisation for primary exposure for use 1 (Meta-SPC 2, 3 and 7)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

For all tasks of scenario 1 for meta-SPC 2, 3 and 7, the estimated inhalation concentration is considered negligeable and therefore below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 2 and 7 are classified Skin corrosive category 1 (H314) and the products for meta-SPC 3 are classified skin irritant (H315). All the products are classified severe eye damage (H318) and are intended to be applied by professional. The diluted products of meta-SPC 3 are classified H318. Considering that, a qualitative risk assessment is performed. Please refer to the tables below.

For the mixing & loading (Meta-SPC 2 and 3) and the pouring (Meta-SPC 7), the professional is using the product for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products of meta-SPC 3 (H315) are used in the same conditions (frequency, duration of exposure) as the products classified as H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).

For the application by pouring of the diluted products of Meta-SPC 3, the professional is using the product for a low duration per day and with PPE. Considering this, the risk is deemed acceptable.

For the application by pouring of the diluted products of meta-SPC 2, the dilutions are not classified, no qualitative assessment is required.

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** Products from Meta SPC 2 and 7 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | |  | | | **Exposure** | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professional | Mixing and loading (meta-SPC 2)  Application in sanitary installations by pouring (meta-SPC 7) | | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min  Application = 10min | Skin exposure through potential liquid spills aroung the bottle and/or due to splashes of the liquid concentrate  (2.2 to 12.5% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency | |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer  (2.2 to 12.5% avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** products from Meta-SPC 3 are skin irritant and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 2 | Professional | Mixing and loading | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min | Skin exposure through potential liquid spills aroung the bottle and/or dur to splashes of the liquid concentrate  (2.6% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer  (2.6% avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** Diluted products from Meta SPC 3 are eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | |  | | | **Exposure** | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Professional | Application in sanitary installations by pouring | | Eye | Frequency: once a day, everyday   Duration:  Application = 10min | Eye exposure through potential splashes or hand to eye transfer  (0.4842% avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency |

**Conclusion for use 1: Disinfection of sanitary installations (toilet bowls, drains, sinks, etc.) – PT 2 (Meta-SPC 2, 3 and 7)**

For products pertaining to **Meta SPC 2**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

For mixing and loading task: gloves, body protection and chemical goggles.

For products pertaining to **Meta SPC 3**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

For mixing and loading task: gloves, body protection and chemical goggles.

For application task: chemical goggles

For products pertaining to **Meta SPC 7**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

For application task: gloves, body protection and chemical goggles.

**Uses 2, 3 and 5: Disinfection of hard surfaces (medical and non-medical sector) – PT 2 and 4 (meta-SPC 1, 2, 3 and 7)**

**Primary exposure**

As the same tasks are performed with products of meta-SPC 1, 2, 3 and 7 for the uses 2, 3 and 5, it has been considered that the same exposure and risk assessment can be done for these uses.

The concentrated products of meta-SPC 1, 2, 3 and 7 are diluted into water prior to their application.

The maximum content of active chlorine expected in the dilution for each meta-SPC and for each use is reported in the table below, as well as the classification of these dilutions (see confidential PAR for detailed explanations):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Uses | Meta-SPC 1 | Meta-SPC 2 | Meta-SPC 3 | Meta-SPC 7 |
| Use 2 | - | 6053 mg/L | 2462 mg/L | 1610 mg/L |
| Use 3 | - | 5299 mg/L | 4842 mg/L | - |
| Use 5 | 4287 mg/L | 6053 mg/L | 4842 mg/L | 1610 mg/L |
| Classification | H314 H318 | NC | H318 | H314 H318 |

The maximum content of available chlorine for each meta-SPC, all uses confonded, is taken into account for the assessment.

The product is diluted manually or (semi) automatically in water according to the claimed doses. Then the professional user applies the diluted product on hard surfaces by different modes of application:

* Spraying using a trigger spray, a compression sprayer (1-3 bar pressure) or a Venturi sprayer (2-6 bar pressure)
* Mopping / Wiping / Scrubbing
* Pouring

According to the applicant, a rinsing step is expected after all the uses of PT4. Therefore, after a contact time of 15min, the product is rinsed off using a wet cloth after application of the product by spraying with a trigger spray, wiping, scrubbing or pouring and using a mop after application by mopping. The product is rinsed with water and using the same apparatus as for the application by a compression sprayer or a Venturi sprayer. This rinsing step is added only for use 5.

Exposure during the cleaning of equipment (bucket, trigger sprayer, mop or cloth) is covered by the exposure during application.

Dermal and inhalation exposure are expected.

A quantitative local risk assessment is performed for inhalation exposure and a qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

**Scenario 2: Disinfection of hard surfaces by spraying**

*Task [2.1] – Mixing and loading*

| **Description of Task [2.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 1, 2, 3 and 7 are diluted in water according to the claimed doses. The dilution step is either done manually if the packaging is less than 20L, or (semi) automatically if the packaging is more than 20L.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of meta-SPC 1, 2, 3 and 7, exposure to inhalation of vapours of HClO is negligeable. Exposure to aerosol is also considered negligeable for manual loading due to to small quantities and for (semi) automated loading as no exposure is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [2.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [2.1] | 1/ No PPE | negligeable |

*Task [2.2] – Application by spraying with a trigger spray*

| **Description of Task [2.2] – Application by spraying with a trigger spray** | | | |
| --- | --- | --- | --- |
| Products of meta-SPC 1, 2, 3 and 7 are diluted in water according to the claimed doses, then the professional user applies the diluted product on hard surfaces using a trigger spray.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified.  As pH > 10 for the dilution of all these meta-SPC, only exposure to aerosols of sodium hypochlorite is expected.  To assess inhalation exposure during the spray application, the **Consumer product spraying and dusting model 2 (hand-held trigger spray)** from BHHEM (p.344), is used.  The exposure value from the model is as follow:   * 10.5 mg/m3 (inhalation)   The maximum concentration of active chlorine in the diluted product ranges between 1610 mg/L, equivalent to 0.161% w/w and 6053 mg/L, equivalent to 0.6053% w/w. The maximum content of 0.6053% w/w active chlorine is used for the calculations. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Maximum sodium hypochlorite concentration in the diluted product (% w/w avCl) | 0.6053% | Applicant’s data |
| Inhalation exposure value (mg/m3) | 10.5 mg/m3 | Consumer product spraying and dusting model 2 |

***Calculations for Task [2.2]***

| **Summary table: estimated exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% avCl)** |
| Task [2.2] | 1/ No PPE | 6.36x10-2 | 0.6053 | |

*Task [2.3] – Application by spraying with a compression sprayer (1-3 bar)*

| **Description of Task [2.3] – Application by spraying with a compression sprayer (1-3 bar)** | | | |
| --- | --- | --- | --- |
| Products of meta-SPC 1, 2, 3 and 7 are diluted in water according to the claimed doses, then the professional user applies the diluted product on hard surfaces using a compression sprayer (1-3 bar pressure).  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified.  As pH > 10 for the products of all these meta-SPC and dilution, only exposure to aerosols of sodium hypochlorite is expected.  To assess inhalation exposure during the spray application, the **Spraying model 1**, from BHHEM (p.281), is used. This model covers the mixing and loading and application tasks. As exposure to aerosol is not expected during mixing and loading, the concentration of active chlorine in the diluted product is used for inhalation.  The exposure value from the model is as follow:   * 104 mg/min (inhalation)   Content of active chlorine in the dilution for meta-SPC 1, 2, 3 and 7 ranges between 0.161% w/w and 0.6053% w/w. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Sodium hypochlorite concentration in the dilution (% w/w avCl) | 0.4287% (meta-SPC 1)  0.6053% (meta-SPC 2)  0.4842% (metaSPC 3)  0.161% (meta-SPC 7) | Applicant’s data |
| Inhalation exposure value (mg/m3) | 104 mg/m3 | Spraying model 1 |
| 2 | Respiratory protective equipement | Min APF 4 (Meta-SPC 2 and 3) | BHHEM |

***Calculations for Task [2.3]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation Concentration (mg/m3)** |
| Task [2.3] | Meta-SPC 1 | |
| 1/ No PPE | 4.46x10-1 |
| Meta-SPC 2 | |
| 1/ No PPE | 6.30x10-1 |
| 2/ APF4 | 1.57x10-1 | |
| Meta-SPC 3 | | |
| 1/ No PPE | 5.04x10-1 |
| 2/ APF 4 | 1.26x10-1 | |
| Meta-SPC 7 | | |
| 1/ No PPE | 1.67x10-1 | |

*Task [2.4] – Application by spraying with a Venturi disinfection plant (meta-SPC 1 only)*

| **Description of Task [2.4] – Application by spraying with a Venturi disinfection plant (meta-SPC 1 only)** | | | |
| --- | --- | --- | --- |
| The applicant proposes that the professional uses a Venturi disinfection plant for the disinfection of buildings mostly destined to the agro-alimentary domain by spraying, after automated mixing and loading. This task is proposed only for foaming products which only corresponds to products of meta-SPC 1.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified.  As pH > 10 for the products of the meta-SPC 1 and dilution, only exposure to aerosols of sodium hypochlorite is expected.  To assess inhalation exposure during the spray application for foaming products, the **Spraying model 11** from BHHEM p298 is used. This model proposes an estimated value for inhalation exposure to chlorine, which is 0.16 mg/m3 of active chlorine (75th percentile).  The maximum concentration of active chlorine in the diluted product is 4287 mg/L equivalent to 0.4287% w/w for meta-SPC1. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Max sodium hypochlorite concentration in the diluted product (% w/w avCl) | 0.4287% (meta-SPC1) | Applicant’s data |
| Inhalation exposure value (mg/m3 of chlorine) | 0.16 mg/m3 | Spraying model 11 |

***Calculations for Task [2.4]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [2.4] | 1/ No PPE | 0.16 | |

*Task [2.5] – Post-application - Rinsing of product with a cloth (use 5 only)*

| **Description of Task [2.5] – Post-application - Rinsing of product with a cloth** |
| --- |
| After a contact time of 15 min, the diluted product applied with a trigger spray is rinsed off with a wet cloth.  After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  Despite the reaction of the active substance with the organic matter and the dilution provided by the rinsing, it is difficult to consider that the solution remaining on the surface is no more classified for dermal route (if the in-use dilution is indeed classified). As a worst-case, a qualitative risk assessment is performed taking into account the classification of the in-use dilution. |

***Calculations for Task [2.5]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [2.5] | 1/ No PPE | negligeable |

*Task [2.6] – Post-application - Rinsing of product with a compression sprayer (use 5 only)*

| **Description of Task [2.6] – Post-application - Rinsing of product with a compression sprayer** |
| --- |
| After a contact time of 15min, the diluted product applied with a compression sprayer is rinsed off with water by the professional user, also using a compression sprayer.  Exposures are via the dermal and inhalation route. After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10. Considering this, exposure through inhalation to vapours during this task is considered negligible, only exposure to aerosol is expected.  The same model is used as for the application by compression sprayer for inhalation: **Spraying model 1** from BHHEM (p.281).  Dermal and inhalation exposure during rinsing is covered by the application of the dilution. As a worst case, the user will be exposed at a concentration not higher than the concentration of avCl in the dilution.  See task [2.3] for calculation. |

*Task [2.7] – Post-application - Rinsing of product with a Venturi disinfection plant (use 5 only)*

| **Description of Task [2.7] – Post-application - Rinsing of product with a Venturi disinfection plant** |
| --- |
| After a contact time of 15min, the diluted product from meta-SPC 1 applied with a Venturi disinfection plant is rinsed off with water by the professional user, also using a Venturi disinfection plant.  Exposures are via the dermal and inhalation route. After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10. Considering this, exposure through inhalation to vapours during this task is considered negligible, only exposure to aerosol is expected.  The same model is used as for the application by spraying for inhalation: **Spraying model 11** from BHHEM (p.298).  Dermal and inhalation exposure during rinsing is covered by the application of the dilution. As a worst case, the user will be exposed at a concentration not higher than the concentration of avCl in the dilution.  See task [2.4] for caclulation |

*Task [2.8] – Post-application – Cleaning equipment (compression sprayer)*

| **Description of Task [2.8] – Post-application – Cleaning equipment** |
| --- |
| The professional user disposes of the diluted product and cleans the equipment (compression sprayer).  Only exposure via dermal route is expected. Inhalation exposure is considered negligeable for this task. As dilution for all meta-SPC has a pH > 10, vapour of HClO are negligeable.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified. |

***Calculations for Task [2.8]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [2.8] | 1/ No PPE | negligeable |

**Scenario 3: Disinfection of hard surfaces by mopping/wiping/scrubbing**

*Task [3.1] – Mixing and loading*

| **Description of Task [3.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 1, 2, 3 and 7 are diluted in water according to the claimed doses. The dilution step is either done manually if the packaging is less than 20L, or (semi) automatically if the packaging is more than 20L.  This task is similar to the Mixing and loading before spraying with a trigger spray. Refer to Task [2.1]. |

*Task [3.2] – Application by mopping/wiping/scrubbing*

| **Description of Task [3.2] – Application by mopping/wiping/scrubbing** |
| --- |
| The professional user applies the dilution (meta-SPC 1, 2, 3 and 7) on hard surfaces with a mop or a cloth.  In an update of the surface disinfection model 1 (discussed in WG II 2018), exposure to aerosols during mopping or wiping activities is considerd negligible. Only exposure to vapours should be considered if the substance is volatile.  As pH for the dilution is above 10 for these meta-SPC, exposure by inhalation to vapours of sodium hypochlorite is not expected.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified. |

***Calculations for Task [3.2]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [3.1] | 1/ No PPE | negligible |

*Task [3.3] – Post-application - Rinsing of product with a cloth (use 5 only)*

| **Description of Task [3.3] – Post-application - Rinsing of product with a cloth** |
| --- |
| After a contact time of 15 min, the diluted product applied by wiping or scrubbing is rinsed off with a wet cloth.  This task is the same as for the rinsing after application by trigger spray. Refer to the Task [2.5]. |

*Task [3.4] – Post-application - Rinsing of product with a mop (use 5 only)*

| **Description of Task [3.4] – Post-application - Rinsing of product with a mop** |
| --- |
| After a contact time of 15 min, the diluted product applied by mopping is rinsed off with water using a mop and bucket.  This task is similar to the rinsing with a cloth. Refer to the Task [2.5]. |

**Scenario 4: Disinfection of hard surfaces by pouring**

*Task [4.1] – Mixing and loading*

| **Description of Task [4.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 1, 2, 3 and 7 are diluted in water according to the claimed doses. The dilution step is either done manually if the packaging is less than 20L, or (semi) automatically if the packaging is more than 20L.  This task is similar to the Mixing and loading before spraying with a trigger spray. Refer to Task [2.1]. |

*Task [4.2] – Application by pouring*

| **Description of Task [4.2] – Application by pouring** |
| --- |
| The diluted products for meta-SPC 1, 2, 3 and 7 are manually poured into hard surfaces, such as drains and sinks, for disinfection, then wiped all over the surfaces with a cloth by the professional user.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of all the meta-SPC concerned, inhalation of vapours of HClO is negligible. Exposure to aerosol is also considered negligeable due to small quantities poured on surface.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified. |

***Calculations for Task [4.2]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** |
| Task [4.2] | 1/ No PPE | negligeable |

*Task [4.3] – Post-application - Rinsing of product with a cloth (use 5 only)*

| **Description of Task [4.3] – Post-application - Rinsing of product with a cloth** |
| --- |
| After a contact time of 15 min, the diluted product applied by pouring is rinsed off with a wet cloth.  This task is the same as for the rinsing after application by trigger spray. Refer to Task [2.5]. |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application) is not relevant.

**Risk characterisation for primary exposure for Uses 2/3/5 (Meta-SPC 1, 2, 3 and 7)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC**  **(%)** |
| **Scenario 2: Application by spraying** | | | | | |
| Task [2.1] | negligeable | | | | nr |
| Task [2.2] | 1/ No PPE | | 0.5 | 6.36x10-2 | 13% |
| Task [2.3] | Meta-SPC 1 | | | | |
| 1/ No PPE | | 0.5 | 4.46x10-1 | 89% |
| Meta-SPC 2 | | | | |
| 1/ No PPE | | 0.5 | 6.30x10-1 | **126%** |
| 2/ RPE (APF4) | | 0.5 | 1.57x10-1 | 31% |
| Meta-SPC 3 | | | | |
| 1/ No PPE | | 0.5 | 5.04x10-1 | **101%** |
| 2/ RPE (APF4) | | 0.5 | 1.26x10-1 | 25% |
| Meta-SPC 7 | | | | |
| 1/ No PPE | | 0.5 | 1.67x10-1 | 33% |
| Task [2.4] | 1/ No PPE | | 0.3 | 1.60x10-1 | 32% |
| Task [2.5] use 5 only | negligeable | | | | nr |
| Task [2.6] use 5 only | Meta-SPC 1 | | | | |
| 1/ No PPE | 0.5 | | 4.46x10-1 | 89% |
| Meta-SPC 2 | | | | |
| 1/ No PPE | 0.5 | | 6.30x10-1 | **126%** |
| 2/ RPE (APF4) | 0.5 | | 1.57x10-1 | 31% |
| Meta-SPC 3 | | | | |
| 1/ No PPE | 0.5 | | 5.04x10-1 | **101%** |
| 2/ RPE (APF4) | 0.5 | | 1.26x10-1 | 25% |
| Meta-SPC 7 | | | | |
| 1/ No PPE | 0.5 | | 1.67x10-1 | 33% |
| Task [2.7] use 5 only | 1/ No PPE | 0.5 | | 1.60x10-1 | 32% |
| Task [2.8] | negligeable | | | | nr |
| **Scenario 3: Application by mopping / wiping / scrubbing** | | | | | |
| Task [3.1] | neligeable | | | | nr |
| Task [3.2] | negligeable | | | | nr |
| Task [3.3] use 5 only | negligeable | | | | nr |
| Task [3.4] use 5 only | negligeable | | | | nr |
| **Scenario 4: Application by pouring** | | | | | |
| Task [4.1] | negligeable | | | | nr |
| Task [4.2] | negligeable | | | | nr |
| Task [4.3] | negligeable | | | | nr |

For meta-SPC 1, 2, 3 and 7, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 1, 2 and 7 are classified Skin corrosive category 1 (H314) and the products for meta-SPC 3 are classified skin irritant (H315). All the products are classified severe eye damage (H318) and are intended to be applied by professional. Considering that, a qualitative risk assement is performed. Please refer to the tables below.

For the mixing and loading task, the professional is using the product for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products of meta-SPC 3 (H315) are used in the same conditions (frequency, duration of exposure) as the products classified as H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).

The diluted products of meta-SPC 1 and 7 are classified Skin corrosive cat 1 (H314) and severe eye damage (H318). The diluted products of meta-SPC 3 are only classified severe eye damage (H318). Considering that, a qualitative risk assement is performed. Please refer to the tables below.

For dilutions of meta-SPC 1 and 7:

For application and rinsing by compression sprayer (spray or foam), the professional is using the product for more than few minutes per day and no high level of containment is expected even if with the use of PPE. Considering this, the risk is not considered as acceptable for dilutions classified H314. As diluted products of meta-SPC 3 are not classified for skin corrosion but only severe eye damage, the risk is deemed acceptable with the use of PPE.

For application by trigger spray, the professional is using the product few minutes per day taking into account that the duration is not 30 min consecutively and with the use of PPE. Considering this, the risk is deemed acceptable. The risk is also considered acceptable during the rinsing with a cloth. Indeed, taking into account the use of PPE and the rinsing with water and the cloth, no direct contact is expected with the dilution.

For application by mopping/scrubbing and rinsing with a mop/brush, the professional will be exposed to the dilution few minutes per day, considering the use of PPE and the RMM to prevent direct contact with the in-use dilution: “A mop/brush with a handle has to be used to apply the diluted solution to avoid exposure” and “do not immerse hands in the diluted solution”. Considering this, the risk is deemed acceptable.

For application by wiping/scrubbing, the professional will be exposed to the dilution few minutes per day, considering the use of PPE and the RMM to prevent direct contact with the in-use dilution: “Pour the solution directly on the surface and wipe with a cloth”. Considering this, the risk is deemed acceptable. The risk is also considered acceptable during rinsing with a cloth, considering the use PPE and the rinsing with water and the cloth. Indeed, no direct contact is expected with the dilution.

For application by pouring and rinsing, the professional is using the product for a low duration per day. Considering the use of PPE and the RMM “Avoid direct contact with the solution to be applied”, the risk is deemed acceptable.

For dilutions of meta-SPC 3:

For all these application tasks, the professional will be exposed to the dilution few minutes per day, considering the use of PPE. Considering this, the risk is deemed acceptable.

For dilutions of meta-SPC 2:

For all these application tasks, the diluted products of meta-SPC 2 are not classified, no qualitative assessment is required.

* + Qualitative risk assessment (inhalation exposure)

Products of meta-SPC 1, 2 and 7 are classified Skin corrosive category 1 (H314) and they are applied by spraying. Therefore, the mention EUH071 is required.

The diluted products of meta-SPC 2, which are sprayed, are not classified H314 anymore therefore qualitative risk assessment is not necessary.

Diluted products of meta-SPC 1 and 7, which are sprayed, are classified H314/H318, a local risk assessment is performed. Please refer to the tables below.

For application by trigger spray, the professional is using the product few minutes per day, taking into account that the duration is not 30 min consecutively and with the use of RPE. Considering this, the risk is deemed acceptable.

For application by compression sprayer (spray or foam), the professional is using the product for more than few minutes per day and no high level of containment is expected even if with the use of RPE. Considering this, the risk is not considered as acceptable.

**Table 1 – Local effects – Qualitative assessment for disinfection of hard surfaces:** Products from Meta SPC 1, 2 and 7 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | |  | | | **Exposure** | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professional | Mixing and loading (meta- SPC 1, 2 and 7) | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min | Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate  (2.2 to 12.5% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day for M&L)  (-) High frequency | |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (2.2 to 12.5% avCl) | Chemical goggles |

**Table 2 – Local effects – Qualitative assessment for disinfection of hard surfaces:** products from Meta-SPC 3 are skin irritant and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 2 | Professional | Mixing and loading | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min | Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate  (2.6%avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day for M&L)  (-) High frequency |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (2.6%avCl) | Chemical goggles |

**Table 3 – Local effects – Qualitative assessment for disinfection of hard surfaces:** Diluted products from Meta SPC 1 and 7 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | |  | | | **Exposure** | | | | | | **Risk** | | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professional | Application and rinsing with a compression sprayer  Application and rinsing with a Venturi spray (only meta-SPC 1) | Skin | Frequency: once a day, everyday   Duration:  120 min | Dermal contact  (0.161 to 0.4287% avCl) | none | | | **Not acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High exposure duration (more than few minutes per day)  (-) High frequency  (-) Spray/foam application with compression/Venturi sprayer | |
| Eye Dam. Cat 1 (H318) | Eye | Eye exposure through aerosols or hand to eye transfer during the different tasks  (2.2 to 12.5% avCl) |
| EUH071 | Inhalation | Aerosols generated |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professionals | Application by trigger spray | Skin | Frequency: once a day, everyday   Duration:  30 min | Dermal contact  (0.161 to 0.4287% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals | | | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (+) Low duration considering not 30min consecutively  (-) Spray application | | |
| Eye Dam. Cat 1 (H318) | Eye | Eye exposure through aerosols or hand to eye transfer during the different tasks  (0.161 to 0.4287% avCl) | Chemical goggles |
| EUH071 | Inhalation | Aerosols generated | Respiratory protective equipment |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professionals | Application by mopping/scrubbing  Post-application – Rinsing with a mop | Skin | Frequency: once a day, everyday   Duration:  Few minutes | Dermal contact  (0.161 to 0.4287% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals   RMM:   * A mop/brush with a handle has to be used to apply the diluted solution to avoid exposure * Do not immerse hands in the diluted solution | | | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (+) Low duration considering the proposed RMM | | |
| Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.161 to 0.4287% avCl) | Chemical goggles |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professionals | Application by wiping/scrubbing  Pos-application – Rinsing with a cloth | Skin | Frequency: once a day, everyday   Duration:  Few minutes | Dermal contact  (0.161 to 0.4287% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals   RMM:   * Pour the solution directly on the surface and wipe with a cloth | | | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (+) Low duration considering the proposed RMM | | |
| Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.161 to 0.4287% avCl) | Chemical goggles |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professionals | Application by pouring | Skin | Frequency: once a day, everyday   Duration:  Few minutes | Dermal contact  (0.161 to 0.4287% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals   RMM:   * Avoid direct contact with the solution to be applied | | | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (+) Low duration | | |
| Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.161 to 0.4287% avCl) | Chemical goggles |

**Table 4 – Local effects – Qualitative assessment for disinfection of hard surfaces:** Diluted products from Meta SPC 3 are severe eye damaging

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Professionals | Application and rinsing with a compression sprayer | Eye | Frequency: once a day, everyday   Duration:  120 min | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.4842%avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (-) High exposure duration  (+) Not classified for skin corrosion |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Professionals | Application with a trigger spray  Rinsing with a cloth | Eye | Frequency: once a day, everyday   Duration:  30 min | Eye exposure through aerosols or hand to eye transfer during the different tasks  (0.4842%avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (-) Low duration considering not 30 min consecutively  (-) Spray application  (+) Not classified for skin corrosion |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Professionals | Application by mopping/ wiping/ pouring  Post-application – Rinsing with a mop or a cloth | Eye | Frequency: once a day, everyday   Duration:  Few minutes to few hours | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.4842%avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * Instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High frequency  (-) High duration  (+) Not classified for skin corrosion |

**Secondary exposure**

**Scenario 5: Exposure of a bystander**

| **Description of Scenario 5** |
| --- |
| The professional bystander present during the application by compression, Venturi sprayer and trigger spray and the rinsing by compression or Venturi sprayer can be exposed by inhalation and dermally to aerosols generated by the spray equipment.  Professional bystander will not be exposed greater than the user performing the task. (See primary exposure) |

**Scenario 6: Contact with wet treated surface (only uses 2 and 3)**

| **Description of Scenario 6** |
| --- |
| The professional/industrial user/bystander can accidently touch the recently treated surface and be dermally exposed to wet diluted product as the suface is not rinsed after contact time for these uses.  A qualitative local risk assessment is performed when the in-use dilutions are classified. |

**Risk characterisation for secondary exposure for uses 2/3/5 (Meta-SPC 1, 2, 3 and 7)**

* + (Semi)-quantitative risk assessment (inhalation exposure) and qualitative local risk assessment (dermal/inhalation)

For application by spraying, inhalation exposure of the bystander is the same as the inhalation exposure of the professional/industrial user (see primary exposure).

For meta-SPC 1, 2, 3 and 7, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

However, for application by spraying and rinsing with a compression sprayer (only use 5) of diluted products of meta-SPC 2 and 3, minimum APF 4 is needed for the professional / industrial bystander. Moreover, dermal exposure to aerosols generated by the spray equipment is also possible for the bystander for meta-SPC 3. Taking this into account, the following risk mitigation measure is required for bystander:

* Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE and PPE as the professional user.

For meta-SPC 1 and 7, RPE is required due to the local risk assessment for application with a trigger spray of corrosive dilutions. Dermal exposure to aerosols generated by the spray equipment is also possible for the bystander for meta-SPC 1, 3 and 7. Taking this into account, the following risk mitigation measure is required for bystander:

* Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.

After application and only for uses 2 and 3, diluted products remaining on the freshly treated surface are classified H314/H318 (meta-SPC 1 and 7) and H318 (meta-SPC 3). Therefore, the following risk mitigation measure is required for bystander:

* Do not touch the surface until it is completely dried

For meta-SPC 1 and 7, as the risk is not acceptable for professionals when applying the product by compression sprayer or Venturi sprayer (only meta-SPC 1) due to local risk assessment, exposure to bystander is not relevant.

**Conclusion for uses 2/3/5: Disinfection of hard surfaces (medical and non-medical sector) – PT 2 and 4 (Meta-SPC 1, 2, 3 and 7)**

For products pertaining to **Meta SPC 1 and 7**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading for all modes of application: gloves, body protection and chemical goggles.
* For application with a trigger spray and rinsing: gloves, body protection, chemical goggles and only for application a respiratory protective equipment against aerosols
* For application by mopping/scrubbing and rinsing with a mop: gloves, body protection and chemical goggles

“A mop/brush with a handle has to be used to apply the diluted solution to avoid exposure”

“Do not immerse hands in the diluted solution”

* For application by wiping/scrubbing and rinsing: gloves, body protection and chemical goggles

“Pour the solution directly on the surface and wipe with a cloth”

* For application by pouring and rinsing: gloves, body protection and chemical goggles

“Avoid direct contact with the solution to be applied”

Risk is acceptable for professional bystander with the following risk mitigation measures:

“Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.”

“Do not touch the surface until it is completely dried” (uses 2 and 3)

For products pertaining to **Meta-SPC 1 and 7**, risk is not acceptable for the application with a **compression sprayer and a Venturi sprayer** (only meta-SPC 1) considering the qualitative risk assessment for local effects.

For products pertaining to **Meta SPC 2**, risk is acceptable considering the semi-quantitative and qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading for all modes of application: gloves, body protection and chemical goggles.
* For application by spraying with a compression sprayer and rinsing with a compression sprayer (only use 5): respiratory protective equipment against aerosols at minima APF 4

Risk is acceptable for professional bystander with the following risk mitigation measures:

“Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user.”

For products pertaining to **Meta SPC 3**, risk is acceptable considering the semi-quantitative and qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading for all modes of application: gloves, body protection and chemical goggles.
* For application by spraying with a compression sprayer and rinsing with a compression sprayer (only use 5): chemical goggles and respiratory protective equipment against aerosols at minima APF 4
* For application by trigger spray, by mopping, wiping, scrubbing and pouring: chemical goggles

Risk is acceptable for professional bystander with the following risk mitigation measures:

“Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE and PPE as the professional user.”

“Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same PPE as the professional user.”

“Do not touch the surface until it is completely dried” (for uses 2 and 3)

**Use 4: Anti-lichen and anti-algae treatment of hard surface (Meta-SPC 5 only)**

**Primary exposure**

**Scenario 7: Anti-lichen and anti-algae treatment of hard surface by spraying**

The professional user is applying the product outdoor with a compression sprayer, on hard surfaces such as wall, floor, roof, etc. as a treatment against lichen and algae. The product from meta-SPC 5 is ready-to-use, so no dilution prior to the application is needed. The claimed dose is 0.1L of product per m2.

The maximum content of active chlorine for meta-SPC 5 is 6% w/w.

The post-application phase include the tasks of rinsing the treated surfaces with water and cleaning the equipement (sprayer).

Dermal and inhalation exposure are expected.

A quantitative local risk assessment is performed for inhalation exposure and a qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product is classified.

*Task [7.1] – Application by spraying with a compression sprayer (1-3 bar)*

| **Description of Task [7.1] – Application by spraying with a compression sprayer (1-3 bar)** | | | |
| --- | --- | --- | --- |
| The professional user loads and applies the concentrated product on hard surfaces using a compression sprayer (1-3 bar pressure).  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified.  As pH > 10 for the products of meta-SPC 5, only exposure to aerosols of sodium hypochlorite is expected.  To assess the inhalation exposure during the spray application, the **Spraying model 1**, from BHHEM (p.281), is used. This model covers the mixing and loading and application tasks.  The exposure value from the model is as follow:   * 104 mg/min (inhalation)   The maximum concentration of active chlorine in the meta-SPC 5 is 6% w/w. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Max Sodium hypochlorite concentration (% w/w avCl) | 6% | Applicant’s data |
| Inhalation exposure value (mg/m3) | 104 mg/m3 | Spraying model 1 |
| 2 | Respiratory protection equipment | Min APF20 | BHHEM |

***Calculations for Task [7.1]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [7.1] | 1/ No PPE | 6.24 |
| 2/ APF 20 | 0.31 | |

*Task [7.2] – Post-application – Rinsing with water*

| **Description of Task [7.2] – Post-application – Rinsing with water** | | | |
| --- | --- | --- | --- |
| After the application of the product, the professional user rinses the treated surfaces with water, also using a compression sprayer.  Exposures are via the dermal and inhalation route. After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10. Considering this, exposure through inhalation to vapours during this task is considered negligible, only exposure to aerosol is expected.  The same model used to assessed the inhalation exposure during the application is used: **Spraying model 1** from BHHEM (p.281)  The exposure value from the model is as follow:   * 104 mg/min (inhalation)   As a worst case, the professional user will be exposed at a concentration not higher than the maximum concentration of active chlorine in the meta-SPC 5, which is 6% w/w. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Max Sodium hypochlorite concentration (% w/w avCl) | 6% | Applicant’s data |
| Inhalation exposure value (mg/m3) | 104 mg/m3 | Spraying model 1 |
| 2 | Respiratory protection equipment | APF20 | BHHEM |

***Calculations for Task [7.2]***

| **Summary table: estimated exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% avCl)** |
| Task [7.2] | 1/ No PPE | 6.24 | 6 |
| 2/ APF 20 | 0.31 | 6 | |

*Task [7.3] – Post-application – Cleaning equipment*

| **Description of Task [7.3] – Post-application – Cleaning equipment** |
| --- |
| The user disposes of the product and cleans the equipment used during the application step (compression sprayer).  Only exposure via dermal route is expected. Inhalation exposure is considered negligeable for this task. As products of meta-SPC 5 have a pH > 10, vapour of HClO are negligeable.  For dermal route exposure, a qualitative local risk assessment is performed as the in-use solution is classified. |

***Calculations for Task [7.3]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Scenario [7.3] | 1/ No PPE | negligeable |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

**Risk characterisation for primary exposure for Use 4 (meta-SPC 5)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** |
| **Scenario 7: Anti-lichen and anti-algae treatment of hard surface by spraying** | | | | |
| Task [7.1] | 1/ No PPE | 0.5 | 6.24 | **1248%** |
| 2/ RPE (APF20) | 0.5 | 0.31 | 62% |
| Task [7.2] | 1/ No PPE | 0.5 | 6.24 | **1248%** |
| 2/ RPE (APF20) | 0.5 | 0.31 | 62% |
| Task [7.3] | negligeable | | | nr |

For all scenarios, the estimated inhalation concentration is below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 5 are classified Skin corrosive category 1 (H314) and severe eye damage (H318). They are used by professionals. Considering that, a qualitative risk assement is performed. Please refer to the table below.

For application by compression sprayer, the professional is using the product for more than few minutes per day and no high level of containment is expected even if with the use of PPE. Considering this, the risk is not considered as acceptable.

* + Qualitative risk assessment (inhalation exposure)

Products of meta-SPC 5 are classified Skin corrosive category 1 (H314) and are applied by spraying. Therefore, the mention EUH071 is required and a qualitative risk assessment is performed. Please refer to the table below.

For application by compression sprayer, the professional is using the product for more than few minutes per day and no high level of containment is expected even if with the use of RPE. Considering this, the risk is not considered as acceptable.

**Table – Local effects – Qualitative assessment for anti-lichen and anti-algae treatment of hard surfaces:** Product from Meta SPC 5 is skin corrosive and eye damaging.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Skin Corr Cat 1 (H314) | 2 | Professional | Application and post application | Skin | Frequency: once a day, everyday   Duration:  Application and rinsing step = 120min  Cleaning equipment = 10min | Dermal contact (6% avCl) | None | | **Not acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (-) High exposure duration (more than few minutes per day)  (-) High frequency  (-) Spraying application |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through aerosols and potential splashes or hand to eye transfer  (6% avCl) |
| HIGH | EUH071 | Inhalation | Inhalation exposure to aerosols  (6% avCl) |

**Secondary exposure**

**Scenario 8: Exposure of a bystander**

| **Description of Scenario 8** |
| --- |
| The professional bystander present during the application or rinsing step can be exposed by inhalation and dermally to aerosols generated by the spray equipment.  Bystander will not be exposed greater than the user performing the task. (See primary exposure) |

**Risk characterisation for secondary exposure for use 4 (meta-SPC 5)**

As the risk is not acceptable for professional when applying the product by compression sprayer due to local risk assessment, exposure to bystander is not relevant.

**Conclusion for use 4: Anti-lichen and anti-algae treatment of hard surface – PT2 (Meta-SPC 5)**

For products pertaining to **Meta SPC 5**, risk is not acceptable considering the qualitative risk assessment for local effects.

**Use 6: Disinfection of equipment/materials by automatic spraying – PT4 (Meta-SPC 1, 2 and 3)**

**Primary exposure**

**Scenario 9: Disinfection of equipment/materials by automatic spraying**

The concentrated products of meta-SPC 1, 2 and 3 are diluted into water prior to their application.

The maximum doses for each meta-SPC is:

* 3780 mg/L as active chlorine equivalent to 0.378% w/w for products of meta-SPC 1
* 3934 mg/L as active chlorine equivalent to 0.3934% w/w for products of meta-SPC2
* 4842 mg/L as active chlorine equivalent to 0.4842% w/w for products of meta-SPC3

The classification of the dilutions (see confidential PAR for detailed explanations) is reported in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta-SPC** | **1** | **2** | **3** |
| Use 6 | 0.3780% | 0.3934% | 0.4842% |
| H314 H318 | NC | H318 |

The professional user is disinfecting the equipments or the materials by placing them in a closed systems, such as tunnels, in which the diluted product from meta-SPC 1, 2 and 3 will be automatically sprayed.

As the spraying is performed automatically in closed systems, the dermal and inhalation exposure during the application is negligeable.

The rinsing is also performed automatically in closed systems, therefore the dermal and inhalation exposure during rinsing is considered negligible.

The post-application phases include the handling of the treated equipments or materials after the application and the cleaning and maintenance of the tunnel.

Only dermal exposure is expected during the different tasks (mixing and loading and post-application).

A qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

*Task [9.1] – Mixing and loading*

| **Description of Task [9.1] – Mixing and loading** |
| --- |
| Products of meta-SPC 1, 2 and 3 are diluted into water at the claimed dose. The dilution step either is done manually if the packaging is less than 20L, or automatically if the packaging is more than 20L.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of meta-SPC 1, 2 and 3, inhalation of vapours of HClO is negligible. Exposure to aerosol is also considered negligeable for manual loading due to to small quantities and for automated loading as non exposure is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [9.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [9.1] | 1/ No PPE | negligeable |

*Task [9.2] – Application by automatic spraying*

| **Description of Task [9.2] – Disinfection by automatic spraying** |
| --- |
| As the spraying is performed automatically in closed systems, the dermal and inhalation exposure during the application is negligeable. |

*Task [9.3] – Post Application – Rinsing*

| **Description of Task [9.3] – Rinsing** |
| --- |
| As it is considered that the rinsing of the equipment or materials is also performed automatically in closed systems, the dermal and inhalation exposure during the rinsing is negligeable. |

*Task [9.4] – Post-application – Handling of the treated equipment/materials*

| **Description of Task [9.4] – Post-application – Handling of the treated equipement/materials** |
| --- |
| The professional manually handles the equipment/materials once they are disinfected and rinsed. As no information is available regarding the efficacy of rinsing, it as been considered that the professional is exposed to the diluted product present on the equipment as a worst-case.  Inhalation exposure is considered negligeable for this task. Due to small quantities of product that stay on the equipment/materials, no vapour is expected.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified. |

***Calculations for Task [9.4]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [9.4] | 1/ No PPE | negligeable |

*Task [9.5] – Post-application – Cleaning or maintenance of tunnel*

| **Description of Task [9.5] – Post-application – Cleaning or maintenance of tunnel** |
| --- |
| The task consists of cleaning or reparing the tunnels or spraying system in which this application step is done.  Only exposure via dermal route is expected. Inhalation exposure is considered negligeable for this task. Due to small quantities of product that stay in the tunnel, no vapour is expected.  For dermal route exposure, a qualitative local risk assessment is needed for the dilutions which are classified. |

***Calculations for Task [9.5]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [9.5] | 1/ No PPE | negligeable |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

**Risk characterisation for primary exposure for Use 6 (Meta-SPC 1, 2 and 3)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

For all tasks of scenario 9 for meta-SPC 1, 2 and 3, the estimated inhalation concentration is considered negligeable and therefore below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 1 and 2 are classified Skin corrosive category 1 (H314) and the products for meta-SPC 3 are classified skin irritant (H315). All the products are classified severe eye damage (H318) and are intended to be applied by professional. Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The professional is using the product for the mixing and loading task for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products of meta-SPC 3 (H315) are used in the same conditions (frequency, duration of exposure) as the products classified as H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).

The diluted products of meta-SPC 1 are classified Skin corrosive cat 1 (H314) and severe eye damage (H318). The diluted products of meta-SPC 3 are only classified severe eye damage (H318). Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The professional is expected to be in contact with the dilution during the post-application tasks for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Please refer to the tables below.

The diluted products of meta-SPC 2 are not classified, no qualitative assessment is required.

* + Qualitative risk assessment (inhalation exposure)

Products of meta-SPC 1 and 2 are classified Skin corrosive category 1 (H314) and they are applied by spraying. Therefore, the mention EUH071 is required. However, the products of meta-SPC 2 are diluted and the dilution which is sprayed is not classified H314 anymore. For the diluted products of meta-SPC 1, which are classified H314/H318, no exposure is expected since the application takes place in a closed system. Therefore qualitative risk assessment is not necessary.

**Table – Local effects – Qualitative assessment for disinfection of equipment/materials by automatic spraying:** Products from Meta SPC 1 and 2 and diluted products of meta-SPC 1 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | |  | **Exposure** | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 4 | Professional | Mixing and loading  Post-application – Handling of treated equipment/ materials & maintenance of tunnel (meta-SPC 1) | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min  Post-application = few minutes | Skin exposure through potential liquid spills around the bottle and/or due to splashes of the liquid concentrate  (0.378% to 12.5% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency | |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  ( 0.378% to 12.5% avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** products from Meta-SPC 3 are skin irritant and severe eye damage

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 4 | Professional | Mixing and loading | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min | through potential liquid spills around the bottle and/or due to splashes of the liquid concentrate  (2.6%avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (2.6%avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** diluted products from Meta-SPC 3 are severe eye damage

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Eye Dam. Cat 1 (H318) | 4 | Professional | Post-application – Handling of treated equipment/ materials & maintenance of tunnel | Eye | Frequency: once a day, everyday   Duration:  Post-application = few minutes | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.4842%avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency |

**Conclusion for use 6: Disinfection of equipment/materials by automatic spraying – PT 4 (Meta-SPC 1, 2 and 3):**

For products pertaining to **Meta SPC 1**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading and post-application tasks: gloves, body protection and chemical goggles.

For products pertaining to **Meta SPC 2**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading: gloves, body protection and chemical goggles.

For products pertaining to **Meta SPC 3**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading: gloves, body protection and chemical goggles.
* For post-application tasks : chemical goggles

**Use 7: Disinfection of equipment/materials by immersion/soaking – PT4 (Meta-SPC 2 and 3)**

**Scenario 10: Disinfection of equipment/materials by dipping**

The professional user is disinfecting the equipments or the materials using an immersion bath containing the diluted product from meta-SPC 2 or 3. Hence, a dilution step, manual or semi-automated, is required before the disinfection.

The maximal dose for each meta-SPC is:

* 6053 mg/L as active chlorine for meta-SPC 2
* 4842 mg/L as active chlorine for meta-SPC 3

The maximum content of available chlorine expected in the dilution and taken into account in the assessment for each meta-SPC is reported in the table below, as well as the classification of these dilutions (see confidential PAR for detailed explanations):

|  |  |  |
| --- | --- | --- |
| **Meta-SPC** | **2** | **3** |
| Use 7 | 0.6053% | 0.4842% |
| NC | H318 |

After immersion, the equipments or the materials are rinsed using an immersion bath containing water.

Exposure during the cleaning of equipement (immersion bath) is covered by the exposure during the application.

Only dermal exposure is expected during the different tasks.

A qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

*Task [10.1] – Mixing and loading*

| **Description of Task [10.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 2 and 3 are diluted into water at the claimed dose. The dilution step either is done manually if the packaging is less than 20L, or (semi) automatically if the packaging is more than 20L.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of all the meta-SPC concerned, inhalation of vapours of HClO is negligible. Exposure to aerosol is also considered negligeable for manual loading due to small quantities and for (semi) automated loading as no exposure is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [10.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [10.1] | 1/ No PPE) | negligeable |

*Task [10.2] – Application by dipping in an immersion bath*

| **Description of Task [10.2] – Application by dipping in an immersion bath** |
| --- |
| After dilution, the professional user disinfects the equipment by dipping it in an immersion bath containing the diluted product.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the dilution for all the meta-SPC concerned, inhalation of vapours of HClO is negligible.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified. |

***Calculations for Task [10.2]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [10.2] | 1/ No PPE | negligeable |

*Task [10.3] – Post-application – Rinsing with water*

| **Description of Task [10.3] – Post-application – Rinsing with water** |
| --- |
| After treatment, the professional user rinses the equipment and materials by dipping them into a bath filled with water.  Inhalation exposure is considered negligeable for this task. Due to small quantities of product that stay on the equipment, no vapour is expected.  For dermal route exposure, a qualitative local risk assessment is performed when the in-use dilutions are classified. |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

**Risk characterisation for primary exposure for Use 7 (Meta-SPC 2 and 3)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

For all tasks of scenario 10 for meta-SPC 2 and 3, the estimated inhalation concentration is considered negligeable and therefore below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 2 are classified Skin corrosive category 1 (H314) and the products for meta-SPC 3 are classified skin irritant (H315). All the products are classified severe eye damage (H318) and are intended to be applied by professional. Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The professional is using the product for mixing and loading for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products of meta-SPC 3 (H315) are used in the same conditions (frequency, duration of exposure) as the products classified as H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).

The diluted products of meta-SPC 3 are classified Severe eye damage (H318). Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The professional will be exposed few minutes per day during the dipping tasks considering the use of PPE. Considering this, the risk is deemed acceptable.

For the application by dipping of the diluted products of meta-SPC 2, the products are not classified, leading to no unacceptable risk

**Table – Local effects – Qualitative assessment for disinfection of equipment/materials by immersion/soaking:** Products from Meta SPC 2 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | |  | | | **Exposure** | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 4 | Professional | Mixing and loading | | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min | Dermal contact  (12.5% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency | |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (12.5% avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of equipment/materials by immersion/soaking:** products from Meta-SPC 3 are skin irritant and eye damaging.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 4 | Professional | Mixing and loading | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10min | Dermal contact  (2.6%avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (2.6%avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of equipment/materials by immersion/soaking:** diluted products from Meta-SPC 3 are eye damaging.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Eye Dam. Cat 1 (H318) | 4 | Professional | Application | Eye | Frequency: once a day, everyday   Duration:  Application = few minutes | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.4842%avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (+) Exposure limited with the use of a basket or another appropriate device  (-) Frequency |

**Conclusion for use 7: Disinfection of equipment / materials by immersion / soaking – PT4 (Meta-SPC 2 and 3)**

For products pertaining to **Meta SPC 2**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading task: gloves, body protection and chemical goggles.

For products pertaining to **Meta SPC 3**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading task: gloves, protective coverall and chemical goggles.
* For application by immersion: chemical goggles

**Use 8: Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) and Use 9: Disinfection of inner surfaces in veterinary water systems – PT4 (Meta SPC 1, 2 and 3)**

In use 8, hard surfaces, such as pipelines, tubes, separatives membranes/ion-exchangers and tanks or filling machines or similar, in food or feed areas (beverage production, milk and dairy production, green house watering, etc.) are disinfected by a cleaning-in-place (CIP) process. In use 9, professionals disinfect inner surfaces in veterinary water systems before the injection of drinkable water into the systems.

In both these uses, products of meta-SPC 1, 2 and 3 are diluted manually or (semi) automatically into water before they are introduced into the systems for treatment. Products of meta-SPC 3 are not claimed for use 9 but they still cover both uses.

The maximum content of active chlorine expected in the dilution for each meta-SPC and for each use is reported in the table below, as well as the classification of these dilutions (see Confidential PAR for detailed explanations):

|  |  |  |  |
| --- | --- | --- | --- |
| Uses | Meta-SPC 1 | Meta-SPC 2 | Meta-SPC 3 |
| Use 8 | 3780 mg/L | 4540 mg/L | 4842 mg/L |
| Use 9 | 4287 mg/L | 4540 mg/L | - |
| Classification | H314 H318 | NC | H318 |

The maximum content of available chlorine for each meta-SPC, all uses confonded, is taken into account for the assessment.

As the treatment is performed automatically, the dermal and inhalation exposure during the application is negligeable.

It is considered that the rinsing is also performed automatically in CIP and after treatment of veterinary water systems. Therefore the dermal and inhalation exposure during rinsing is considered negligible.

The post-application phases include the cleaning or repair of reservoir/ stock tank/ pump.

Dermal and inhalation exposure is expected during the different tasks.

A quantitative local risk assessment is performed for inhalation exposure and a qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

**Scenario 11: Disinfection by cleaning-in-place (CIP) and automatic circulation into veterinary water systems**

*Task [11.1] – Mixing and loading*

| **Description of Task [11.1] – Mixing and loading** |
| --- |
| Products of meta-SPC 1, 2 and 3 are diluted manually in water according to the claimed doses and load into the system, if the packaging is less than 20L.  As there are packaging of more than 20L available for the products of meta-SPC 1, 2 and 3, an automated mixing and loading is also considered. Specifically, the professional connects pump lines to the container of the concentrated product.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of all the meta-SPC concerned, inhalation of vapours of HClO is negligible. Exposure to aerosol is also considered negligeable for manual loading due to small quantities and for (semi) automated loading as no exposure is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [11.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [11.1] | 1/ No PPE | negligeable |

*Task [11.2] – Application: Disinfection by cleaning-in-place (CIP) and automatic circulation into veterinary water systems*

| **Description of Task [11.2] – Application: Disinfection by cleaning-in-place (CIP) and automatic circulation into veterinary water systems** |
| --- |
| As the disfection is performed automatically in CIP and veterinary water systems, the dermal and inhalation exposure during the application is negligeable. |

*Task [11.3] – Post Application – Rinsing*

| **Description of Task [11.3] – Post-application – Rinsing** |
| --- |
| It is considered that the rinsing is also performed automatically in CIP and veterinary water systems, therefore the dermal and inhalation exposure during the rinsing is negligeable. |

*Task [11.4] – Post-application – Repair or cleaning of dosing pump*

| **Description of Task [11.4] – Post-application – Repair or cleaning of dosing pump** | | | |
| --- | --- | --- | --- |
| The user can be in contact with the product during the repair or cleaning the dosing pump.  Exposure via dermal and inhalation route is expected. As products for all meta-SPC have a pH > 10, vapour of HClO are negligeable, only exposure by inhalation to aerosol is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified.  To assess inhalation exposure, the **Mixing and loading model 7 (manual liquid)** from BHHEM (p.277), is used.  The exposure value from the model is as follow:   * 0.94 mg/m3 (inhalation)   Content of active chlorine in the products of meta-SPC 1, 2 and 3 ranges between 2.6% and 12.5% w/w. Calculation for inhalation exposure is made with 12.5% w/w active chlorine, which covers all these meta-SPC. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Sodium hypochlorite concentration (% w/w avCl) | 12.5% | Applicant’s data |
| Inhalation exposure value (mg/m3) | 0.94 mg/m3 | Mixing and loading model 7 |

***Calculations for Task [11.4]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [11.4] | 1/ No PPE | 1.18x10-1 |

*Task [11.5] – Post-application – Repair or cleaning of circuit system*

| **Description of Task [11.5] – Post-application – Repair or cleaning of circuit system** |
| --- |
| The user can be in contact with the diluted product during the repair or cleaning of circuit system. As no information is available regarding the efficacy of rinsing, it as been considered that the professional is exposed to the diluted product during the repair or cleaning of circuit system as a worst-case.  Only exposure via dermal route is expected. Inhalation exposure is considered negligeable for this task. Due to small quantities of product that stay in the circuit system, no vapour is expected.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [11.5]***

| **Summary table: estimated exposure from professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Scenario [11.5] | 1/ No PPE | negligeable |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

**Risk characterisation for primary exposure for uses 8 and 9 (Meta SPC 1, 2 and 3)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC (%)** |
| **Scenario 11: Disinfection by cleaning-in-place (CIP) and automatic circulation into veterinary water systems** | | | | |
| Task [11.1] | negligeable | | | **nr** |
| Task [11.2] | Negligeable | | | Nr |
| Task [11.3] | Negligeable | | | Nr |
| Task [11.4] | 1/ No PPE | 0.5 | 1.18x10-1 | 24% |
| Task [11.4] | negligeable | | | nr |

For all tasks of scenario 11 for meta-SPC 1, 2 and 3, the estimated inhalation concentration is below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal/inhalation exposure)

The products of meta-SPC 1 and 2 are classified Skin corrosive category 1 (H314) and the products for meta-SPC 3 are classified skin irritant (H315). All the products are classified severe eye damage (H318) and are intended to be applied by professional. Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The professional is using the product for the mixing and loading task for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products of meta-SPC 3 (H315) are used in the same conditions (frequency, duration of exposure) as the products classified as H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).

For the maintenance of dosinf pump, as potential exposure to aerosols is expected, a respiratory protective equipment is added for products classified H314 (meta-SPC 1).

The diluted products of meta-SPC 1 are classified Skin corrosive cat 1 (H314) and severe eye damage (H318). The diluted products of meta-SPC 3 are only classified severe eye damage (H318). Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The professional is expected to be in contact with the dilution during the maintenance of circuit system for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Please refer to the tables below.

**Table – Local effects – Qualitative assessment for disinfection of hard surfaces in food and feed areas by CIP and disinfection inner surfaces in veterinary water systems:** Products from Meta SPC 1 and 2 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professional | Mixing and loading  Post application: cleaning / maintenance of the dosing pump | Skin / inhalation | Frequency: once a day, everyday   Duration:  Mixing & loading = 10 min  Post application = few minutes | Dermal contact  (6.3% to 12.5% avCl)  Inhalation | Gloves  Skin coverage  Eye protection  Optional face shield  Respiratory protective equipment | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE/RPE  (+) Low exposure duration (few min per day)  (-) Frequency  (-) Potential exposure to aerosols | |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (6.3% to 12.5% avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of hard surfaces in food and feed areas by CIP and disinfection of inner surfaces in veterinary water systems:** products from Meta-SPC 3 are skin irritant and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 2 | Professional | Mixing and loading  Post application: cleaning / maintenance of the dosing pump | Skin | Frequency: once a day, everyday   Duration:  Mixing & loading = 10 min  Post application = few minutes | dermal contact  (2.6%avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**  (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration/frequency (few min per day)  (-) Frequency |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (2.6%avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of hard surfaces in food and feed areas by CIP and disinfection inner surfaces in veterinary water systems:** Diluted products from Meta SPC 1 are skin corrosive and eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Skin Corr, Cat 1 (H314) | 2 | Professional | Post application: cleaning / maintenance of circuit system | Skin | Frequency: once a day, everyday   Duration:  Post application = few minutes | Dermal contact  (0.4287% avCl) | Gloves  Skin coverage  Eye protection  Optional face shield | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency | |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.4287% avCl) | Chemical goggles |

**Table – Local effects – Qualitative assessment for disinfection of hard surfaces in food and feed areas by CIP and disinfection inner surfaces in veterinary water systems:** Diluted products from Meta SPC 3 are eye damaging

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | | | **Risk** | |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant PPE** | **Relevant RMM** | **Conclusion on risk** | |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Professional | Post application: cleaning / maintenance of circuit system | Eye | Frequency: once a day, everyday   Duration:  Post application = few minutes | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.4842% avCl) | Chemical goggles | Labelling   * Labelling according to CLP   Trained personnel   * Professional workers * instructions for use minimizing exposure for professionals | **Acceptable**   (+) Professionals following instructions for use and RMM on the label  (+) Professionals using PPE  (+) Low exposure duration (few min per day)  (-) Frequency | |

**Conclusion for use 8: Disinfection of hard surfaces in food and feed areas by CIP and use 9: Disinfection of inner surfaces in veterinary water systems – PT4 (Meta-SPC 1, 2 and 3)**

For products pertaining to **Meta SPC 1**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading task and maintenance of circuit system: gloves, body protection and chemical goggles.
* For maintenance of dosing pumps: gloves, body protection, chemical goggles and respiratory protective equipment against aerosols

For products pertaining to **Meta SPC 2**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading task: gloves, body protection and chemical goggles.
* For maintenance of dosing pumps: gloves, body protection, chemical goggles and respiratory protective equipment against aerosols

For products pertaining to **Meta SPC 3**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

* For mixing and loading task and maintenance of dosing pumps: gloves, body protection and chemical goggles.
* For maintenance of circuit system: chemical goggles

***Non-professional exposure***

**Use 1: Disinfection of sanitary installations (toilet bowls, drains, sinks, etc.) – PT 2 (Meta-SPC 4 and 6)**

**Primary exposure**

**Scenario 12: Disinfection of sanitary installations by pouring**

The concentrated products of meta-SPC 4 and 6 are diluted into water prior to their application.

The maximal dose for each meta-SPC is:

* 2149 mg/L as active chlorine for meta-SPC 4
* 2270 mg/L as active chlorine for meta-SPC 6

The maximum content of available chlorine expected in the dilution and taken into account in the assessment for each meta-SPC is reported in the table below, as well as the classification of these dilutions (see confidential PAR for detailed explanations):

|  |  |  |
| --- | --- | --- |
| **Meta-SPC** | **4** | **6** |
| Use 1 | 0.2149% | 0.227% |
| H318 | H318 |

The product is diluted in water according to the claimed doses of the applicant, then manually poured into sanitary installations, such as toilet bowls, drains, sinks.

Exposure during the cleaning of equipment (bucket) is covered by the exposure during the application.

Only dermal exposure is expected during the different tasks.

A qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

*Task [12.1] – Mixing and loading*

| **Description of Task [12.1] – Mixing and loading** |
| --- |
| According to the ConsExpo Disinfectant Products Factsheet, during the mixing and loading of a liquid, dermal exposure can occur.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of meta-SPC 4 and 6, vapours of HClO are negligeable.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [12.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from non professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [12.1] | 1/ No PPE | Negligeable |

*Task [12.2] – Application by pouring*

| **Description of Task [12.2] – Application by pouring** |
| --- |
| The diluted product from meta-SPC 4 and 6 is manually poured in sanitary installations (toilet bowls, drains, sinks, etc.).  During the application, only dermal exposure to the product is expected and a qualitative local risk assessment is performed as the different meta-SPC are classified.  Exposure by inhlation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of the meta-SPC 4 and 6, vapours of HClO are negligeable. |

***Calculations for Task [12.2]***

| **Summary table: estimated exposure from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [12.2] | 1/ No PPE | Negligeable |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application) is not relevant.

**Risk characterisation for primary exposure for use 1 (Meta-SPC 4 and 6)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

For all tasks of scenario 12 for meta-SPC 4 and 6, the estimated inhalation concentration is considered negligeable and therefore below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 4 and 6 are classified Skin irritant (H315) and severe eye damage (H318). Also, these products are intended to be used by non-professionals. Considering that, a qualitative risk assement is performed. Please refer to the tables below.

The non-professional is using the product for mixing and loading for a moderate frequency and for a low duration per day. Considering this and the additional RMM “washing on hands after use” and “avoid contact with eyes”, the risk is deemed acceptable.

Product of meta-SPC 6 can be contained in a berlingot packaging, which can lead to the pouring of the product on hands during the opening. As the exposure to the product would only last for a few minutes, that there is no direct exposure to the eyes and that a washing on hands is required after use, the risk is also deemed acceptable for the berlingot packaging.

The diluted products of meta-SPC 4 and 6 are classified severe eye damage (H318). Considering that, a qualitative risk assessment is performed. Please refer to tables below.

The non-professional will be exposed few minutes during the pouring in sanitary installations. Considering this and the additional RMM “washing on hands after use” and “avoid contact with eyes”, the risk is deemed acceptable.

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** products from Meta-SPC 4 and 6 are skin irritant and eye damaging.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM** | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 2 | Non-professional | Mixing and loading | Skin | Frequency: less than once a week   Duration:  Mixing & loading = 1.33min  Used in low duration | Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate  (2.6% to 4.8% w/w avCl) | No PPE  Labelling   * Labelling according to CLP * Instructions for use and storage * “Washing on hands after use” * “Avoid contact with eyes”   Packaging:   * Child-proof closure | **Acceptable with implemented RMM:**  (+) instruction of use and RMM on the label (washing on hands after use, do not touch the eyes)  (+) Low exposure duration (few min per day)  (-) moderate frequency  (+) child-proof closure  (+) no children or infant exposure  (-) Mode of application (the product should be loaded undiluted a first time for measurement and then in a bottle leading to an increase of potential dermal exposure through spills and splashes)  (-) Berlingot (meta-SPC 6) |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer  (2.6% to 4.8% w/w avCl) |

**Table – Local effects – Qualitative assessment for disinfection of sanitary installations:** diluted products from Meta-SPC 4 and 6 are eye damaging.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Non-professional | Application by pouring | Eye | Frequency: less than once a week   Duration:  Few minutes or less | Eye exposure through potential splashes or hand to eye transfer  (0.2149% to 0.227% w/w avCl) | No PPE  Labelling   * Labelling according to CLP * Instructions for use and storage * “Washing on hands after use” * “Avoid contact with eyes”   Packaging:   * Child-proof closure | **Acceptable with implemented RMM:**  (+) instruction of use and RMM on the label (washing on hands after use, do not touch the eyes)  (+) Low exposure duration (few min per day)  (-) moderate frequency  (+) child-proof closure  (+) no children or infant exposure |

**Conclusion for use 1: Disinfection of sanitary installations – PT 2 (Meta-SPC 4 and 6)**

For products pertaining to **Meta SPC 4 and 6**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Washing on hands after use

- Avoid contact with eyes

**Uses 2 and 5: Disinfection of hard surfaces (non-medical sector) - PT 2 and 4 (Meta-SPC 4 and 6)**

**Primary exposure**

As the same tasks are performed with products of meta-SPC 4 and 6 and same application dose are claimed for the uses 2 and 5, it has been considered that the same exposure and risk assessment can be done for both of these uses.

The concentrated products of meta-SPC 4 and 6 are diluted into water prior to their application.

The maximum doses for each meta-SPC is:

* 2149 mg/L as active chlorine for meta-SPC 4
* 2240 mg/L as active chlorine for meta-SPC 6

The maximum content of available chlorine for both meta-SPC is taken into account for the assessment for each meta-SPC and is reported in the table below, as well as the classification of these dilutions (see confidential PAR for detailed explanations):

|  |  |  |
| --- | --- | --- |
| **Meta-SPC** | **4** | **6** |
| Uses 2 and 5 | 0.2149% | 0.227% |
| H318 | H318 |

The product is diluted in water according to the claimed doses of the applicant. Then the non professional user applies the diluted product on hard surfaces by different modes of application:

* Spraying using a trigger spray
* Mopping / Wiping / scrubbing
* Pouring

After a contact time of 15min, the product is rinsed off using a wet cloth or mop.

Exposure during the cleaning of equipment (bucket, mop, cloth) is covered by the exposure during the application.

Dermal and inhalation exposure are expected.

A quantitative local risk assessment is performed for inhalation exposure and a qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl) when the product or the dilution is classified.

**Scenario 13: Disinfection of hard surfaces by spraying**

*Task [13.1] – Mixing and loading*

| **Description of Task [13.1] – Mixing and loading manual** |
| --- |
| According to the ConsExpo Disinfectant Products Factsheet, during the mixing and loading of a liquid, dermal exposure can occur.  Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of meta-SPC 4 and 6, vapours of HClO are negligeable.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified. |

***Calculations for Task [13.1]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [13.1] | 1/ No PPE | Negligeable |

*Task [13.2] – Application by spraying with a trigger spray*

| **Description of Task [13.2] – Application by spraying with a trigger spray** | | | |
| --- | --- | --- | --- |
| The non-professional user applied the diluted product on surfaces using a trigger spray. Dermal and inhalation exposure is expected during the spray application.  For dermal route exposure, a qualitative local risk assessment is performed as the different meta-SPC are classified.  As pH > 10 for the dilution of meta-SPC 4 and 6, only exposure to aerosols of sodium hypochlorite is expected.  To assess inhalation exposure during the spray application, the **Consumer product spraying and dusting model 2 (hand-held trigger spray)** from BHHEM (p.344), is used.  The exposure value from the model is : 10.5 mg/m3 (inhalation) The concentration of active chlorine in the dilution is 0.2149% w/w for meta-SPC 4 and 0.227% w/w for meta-SPC 6. The maximum concentration of 0.227% w/w active chlorine is used for the determination of inhalation exposure. | | | |
| **Tier** | **Parameters** | **Value** | **Source** |
| 1 | Maximum sodium hypochlorite concentration (%w/w avCl) | 0.227% | Applicant’s data |
| Inhalation exposure value (mg/m3) | 10.5 mg/m3 | Consumer product spraying and dusting model 2 |

**Calculations for Task [13.2]**

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from non professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [13.2] | 1/ No PPE | 2.38x10-2 |

*Task [13.3] – Post-application - Rinsing of product with a cloth*

| **Description of Task [13.3] – Post-application - Rinsing of product with a cloth** |
| --- |
| After a contact time of 15 min, the diluted product applied with a trigger spray is rinsed off with a wet cloth.  After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10.  Considering this, exposure through inhalation to vapours during this task is considered negligible.  According to the ConsExpo Disinfectant Products Factsheet (4.2.2.3), during rinsing, dermal exposure can occur.  During this task, dermal exposure is covered by the application of the dilution. As a worst-case, the non professional user will be exposed at a concentration not higher than the concentration of active chlorine in the dilution.  A qualitative local risk assessment is performed as the different dilutions of the meta-SPC are classified. |

***Calculations for Task [13.3]***

| **Summary table: estimated exposure from non professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [13.3] | 1/ No PPE | negligeable |

**Scenario 14: Disinfection of hard surfaces by mopping/wiping/scrubbing**

*Task [14.1] – Mixing and loading*

| **Description of Task [14.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 4 and 6 are diluted in water according to the claimed doses.  This task is the same as for the mixing and loading before application by trigger spray. Refer to the Task [13.1]. |

*Task [14.2] – Application of the product by mopping* / wiping / scrubbing

| **Description of Task [14.2] – Application of the product by mopping / wiping / scrubbing** |
| --- |
| The non-professional user applies the diluted product using a mop, brush or a cloth. Dermal exposure is expected during the application.  According to the ConsExpo Disinfectant Products Factsheet, during application, dermal exposure can occur.  Exposure by inhlation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of the meta-SPC 4 and 6, vapours of HClO are negligeable.  For dermal route exposure, a qualitative local risk assessment is performed as the different dilutions of the meta-SPC are classified. |

***Calculations for Task [14.2]***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: estimated exposure concentration from non professional uses** | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** | **Estimated dermal concentration (% avCl)** |
| Task [14.2] | 1/ No PPE | Negligeable | 0.227 |

*Task [14.3] – Post-application - Rinsing of product with a cloth*

| **Description of Task [14.3] – Post-application - Rinsing of product with a cloth** |
| --- |
| After a contact time of 15 min, the diluted product applied by wiping or scrubbing is rinsed off with a wet cloth.  This task is the same as for the rinsing after application by trigger spray. Refer to the Task [13.3].  Normally no rinsing is required after mopping according to the ConsExpo Disinfectant Products Factsheet. |

**Scenario 15: Disinfection of hard surfaces by pouring**

*Task [15.1] – Mixing and loading*

| **Description of Task [15.1] – Mixing and loading** |
| --- |
| Before use, products of meta-SPC 4 and 6 are diluted in water according to the claimed doses.  This task is the same as for the mixing and loading before application by trigger spray. Refer to the Task [13.1]. |

*Task [15.2] – Application of the product by pouring*

| **Description of Task [15.2] – Application of the product by pouring** |
| --- |
| The non-professional user pours the diluted product into hard surfaces, such as sinks and drains, for disinfection, then he wipes the product with a cloth.  Exposure by inhlation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the products of the meta-SPC 4 and 6, vapours of HClO are negligeable.  For dermal route exposure, a qualitative local risk assessment is performed as the different dilutions of the meta-SPC are classified. |

***Calculations for Task [15.2]***

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure concentration from non professional uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration (mg/m3)** |
| Task [15.2] | 1/ No PPE | Negligeable |

*Task [15.3] – Post-application - Rinsing of product with a cloth*

| **Description of Task [15.3] – Post-application - Rinsing of product with a cloth** |
| --- |
| After a contact time of 15 min, the diluted product applied by pouring is rinsed off with a wet cloth.  This task is the same as for the rinsing after application by trigger spray. Refer to the Task [13.3]. |

**Combined scenarios**

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.

For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application) is not relevant.

**Risk characterisation for primary exposure for uses 2 and 5**

* + (Semi)-quantitative risk assessment (inhalation exposure)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **(mg/m3)** | **Estimated concentration (mg/m3)** | **Estimated concentration / AEC**  **(%)** |
| **Scenario 13: Application by spraying** | | | | |
| Task [13.1] | negligeable | | | nr |
| Task [13.2] | 1/ No PPE | 0.5 | 2.38x10-2 | 5% |
| Task [13.3] | negligeable | | | nr |
| Task [13.4] | negligeable | | | nr |
| **Scenario 14: Application by mopping / wiping / scrubbing** | | | | |
| Task [14.1] | negligeable | | | nr |
| Task [14.2] | negligeable | | | nr |
| Task [14.3] | negligeable | | | nr |
| Task [14.4] | negligeable | | | nr |
| **Scenario 15: Application by pouring** | | | | |
| Task [15.1] | negligeable | | | nr |
| Task [15.2] | negligeable | | | nr |
| Task [15.3] | negligeable | | | nr |
| Task [15.4] | negligeable | | | nr |

For all scenarios, the estimated inhalation concentration is below the AEC of sodium hypochlorite.

* + Qualitative risk assessment (dermal exposure)

The products of meta-SPC 4 and 6 are classified Skin irritant (H315) and severe eye damage (H318). Also, these products are intended to be used by non-professionals. Considering that, a qualitative risk assement is performed. Please refer to the table below.

The non-professional is using the product during mixing and loading for a moderate frequency and for a low duration per day. Considering this and the additional RMM “washing on hands after use” and “avoid contact with eyes”, the risk is deemed acceptable.

Product of meta-SPC 6 can be contained in a berlingot packaging, which can lead to the pouring of the product on hands during the opening. As the exposure to the product would only last for a few minutes, that there is no direct exposure to the eyes and that a washing on hands is required after use, the risk is also deemed acceptable for the berlingot packaging.

The diluted products of meta-SPC 4 and 6 are classified severe eye damage (H318). Considering that, a qualitative risk assessment is performed. Please refer to tables below.

For the application with a trigger spray, these dilutions, classified severe eye damage, are sprayed for 30 minutes continuously by non-professional users leading to high exposure of the dilution. Considering this, the risk is not acceptable.

For the application by mopping/wiping/scrubbing and rinsing, the diluted products are expected to be used more than few minutes per day. However, as the dilutions are only classified for eye, the exposure is limited and can occur only through potential splashes or hand to eye transfer. Considering this and the additional RMM “washing on hands after use” and “avoid contact with eyes”, the risk is deemed acceptable.

For the application by pouring and rinsing, the non-professional will be exposed few minutes or less during the application. Considering this and the additional RMM “washing on hands after use” and “avoid contact with eyes”, the risk is deemed acceptable.

**Table – Local effects – Qualitative assessment for disinfection of hard surfaces:** products from Meta-SPC 4 and 6 are skin irritant and eye damaging.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM** | **Conclusion on risk** |
| LOW | Skin Irrit Cat 2 (H315) | 2 | Non-professional | Mixing and loading | Skin | Frequency: everyday   Duration:  Mixing & loading = 1.33min  Used in low duration | Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate  (2.6% to 4.8% w/w avCl) | No PPE  Labelling   * Labelling according to CLP * Instructions for use and storage * “Washing of hands after use” * “avoid contact with eye”   Packaging:   * Child-proof closure | **Acceptable with implemented RMM:**  (+) instruction of use and RMM on the label  (+) Low exposure duration (few min per day)  (-) Frequency  (+) child-proof closure  (+) no children or infant exposure  (-) Berlingot (meta-SPC 6) |
| HIGH | Eye Dam. Cat 1 (H318) | Eye | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (2.6% to 4.8% avCl) |

**Table – Local effects – Qualitative assessment for disinfection of hard surfaces:** diluted products from Meta-SPC 4 and 6 are eye damaging.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| **Hazard category** | **Effects in terms of C&L** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposure routes** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM** | **Conclusion on risk** |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Non-professional | Application with a trigger spray | Eye | Frequency: everyday   Duration:  30 min | Eye exposure through aerosols or hand to eye transfer during the different tasks  (0.2149% to 0.227% avCl) | None | **Not acceptable**  (+) instruction of use and RMM on the label  (-) Exposure duration  (-) Frequency  (-) Spraying application  (+) child-proof closure  (+) no children or infant exposure |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Non-professional | Application by mopping/ wiping/ scrubbing | Eye | Frequency: everyday   Duration:  No data | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.2149% to 0.227% avCl) | No PPE  Labelling   * Labelling according to CLP * Instructions for use and storage * “Washing of hands after use” * “avoid contact with eye”   Packaging:   * Child-proof closure | **Acceptable with implemented RMM:**  (+) instruction of use and RMM on the label  (-) exposure duration (equal to or less than few min per day cannot be ensure)  (-) frequency  (+) child-proof closure  (+) no children or infant exposure |
| HIGH | Eye Dam. Cat 1 (H318) | 2 | Non-professional | Application by pouring | Eye | Frequency: everyday   Duration:  Few minutes | Eye exposure through potential splashes or hand to eye transfer during the different tasks  (0.2149% to 0.227% avCl) | No PPE  Labelling   * Labelling according to CLP * Instructions for use and storage * “Washing of hands after use” * “avoid contact with eye”   Packaging:   * Child-proof closure | **Acceptable with implemented RMM:**  (+) instruction of use and RMM on the label  (+) Low exposure duration (equal to or less than few min per day)  (-) frequency  (+) child-proof closure  (+) no children or infant exposure |

**Conclusion for Uses 2 and 5: Disinfection of hard surfaces (non-medical sector) - PT2 and 4 (Meta-SPC 4 and 6)**

For products pertaining to **Meta SPC 4 and 6**, risk is acceptable **for application by mopping/ wiping/ scrubbing and pouring** considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

* Washing on hands after use
* Avoid contact with eyeeyes

For products pertaining to **Meta SPC 4 and 6**, risk is not acceptable **for application by spraying** considering the qualitative risk assessment for local effects.

***General public - Secondary exposure***

**Scenario 16: Exposure of a bystander**

| **Description of Scenario [16]** |
| --- |
| Bystander present during the application by spraying can be exposed by inhalation and dermally to aerosols generated by the spray equipment.  Bystander will not be exposed by inhalation greater than the user performing the task. (See primary exposure) |

**Scenario 17: Dermal exposure of the general public to the wet product and oral exposure due to hand-to-mouth transfer**

| **Description of Scenario [17] – Dermal exposure of the general public to the wet product and oral exposure due to hand-to-mouth transfer** |
| --- |
| General public can touch the wet surface during the contact time of the dilution for meta SPC 1, 2, 3, 4, 5, 6 and 7.  Infant after touching the wet surface can be exposed orally to avCl after hand to mouth transfer.  As the in-use dilution of meta-SPC 1, 3, 4, 5, 6 and 7 for all uses are classified, a qualitative risk assessment has to be performed.  No qualitative assessment is necessary for meta-SPC 2, as the in-use dilutions are not classified for all uses. |

**Risk characterisation for general public for uses 1, 2, 3, 4, 5, 6 and 7 (Meta-SPC 1, 2, 3, 4, 5, 6 and 7)**

* + (Semi)-quantitative risk assessment (inhalation exposure)

Inhalation exposure of the bystander is the same as the inhalation exposure of the user (see primary exposure).

For all meta-SPC involved, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all tasks.

However, for meta-SPC 2 and 3 (uses 2, 3 and 5), application and rinsing with compression sprayer, the estimated inhalation concentration is below the AEC of sodium hypochlorite with a RPE. Moreover, dermal exposure to aerosols generated by the spray equipment is also possible for the general public for meta-SPC 3. Therefore the following risk mitigation measure is required for general public for meta-SPC 2 and 3:

* Do not be present in the treatment area during disinfection process with a compression sprayer.

For meta-SPC 1 and 7, RPE is required due to the local risk assessment for application with a trigger spray of corrosive dilutions. Dermal exposure to aerosols generated by the spray equipment is also possible for the general public for meta-SPC 1, 3 and 7. Taking this into account, the following risk mitigation measure is required for the general public for meta-SPC 1, 3 and 7:

Do not be present in the treatment area during disinfection process by trigger spray.

As the risk is not acceptable for professional when applying the product by compression sprayer due to local risk assessment for meta-SPC 1, 5 and 7, exposure to bystander/general public is not relevant.

* + Qualitative risk assessment (dermal and oral exposure)

Diluted products of meta-SPC 1 and 7 are classified H314/H318 and diluted products of meta-SPC 3, 4 and 6 are only classified H318. Therefore the following risk mitigation measures are required for general public for meta-SPC 1, 3, 4, 6 and 7 for disinfection of hard surfaces:

* Do not touch the surface until it is rinsed and totally dried;
* Children should not be present during disinfection and until the surface is rinsed and dry

For meta-SPC 2, the dilution applied is not classified leading to no unacceptable risk.

As the risk is not acceptable for professional when applying the product by compression sprayer due to local risk assessment for meta-SPC 1, 5 and 7, exposure to general public is not relevant.

**Overall conclusion on the risk assessment for human health from local exposure**

**Professional**

|  |  |  |  |
| --- | --- | --- | --- |
| **Overall conclusion on the risk assessment for human health from systemic and local exposure** | | | |
| **Use number** | **Use description** | **Conclusion** | **Set of RMMs** |
| Use 1 | Disinfection of sanitary installations – Professionals  Meta-SPC 2 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles |
| Disinfection of sanitary installations – Professionals  Meta-SPC 3 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application by pouring, wear chemical goggles |
| Disinfection of sanitary installations – Professionals  Meta-SPC 7 (RTU) | Acceptable,  with application of RMM and PPE | User:  For application by pouring, wear gloves, body protection and chemical goggles |
| Uses 2/3 | Disinfection of hard surfaces (medical and non-medical sector) – Professionals  Application with a trigger spray  Application mopping/ wiping/ scrubbing  Application by pouring  Meta-SPC 1 and 7 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application with a trigger spray, wear gloves, body protection, chemical goggles and respiratory protective equipment against aerosols  For application by mopping/scrubbing, wear gloves, body protection and chemical goggles  “A mop/brush with handle has to be used to apply the diluted solution to avoid exposure”  “Do not immerse hands in the diluted solution”  For application by wiping/scrubbing, wear gloves, body protection and chemical goggles  “Pour the solution directly on the surface and wipe with a cloth”  For application by pouring, wear gloves, body protection and chemical goggles  “Avoid direct contact with the solution to be applied”  Professional bystander:  “Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.”  “Do not touch the surface until it is completely dried” (uses 2 and 3 meta-SPC 7)  General public:  “Do not be present in the treatment area during disinfection process by trigger spray.”  “Do not touch the surface until it is rinsed and totally dried”  “Children should not be present during disinfection and until the surface is rinsed and dry” |
| Disinfection of hard surfaces (medical and non-medical sector) – Professionals  Application with a compression sprayer and a Venturi sprayer  Meta-SPC 1 and 7 | **Not acceptable** |  |
| Disinfection of hard surfaces (medical and non-medical sector) – Professionals  All modes of application  Meta-SPC 2 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application by spraying with a compression sprayer and rinsing with a compression sprayer (only use 5), wear respiratory protective equipment against aerosols at minima APF 4  Professional bystander:  “Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user.”  General public:  “Do not be present in the treatment area during disinfection process by compression sprayer.” |
| Disinfection of hard surfaces (medical and non-medical sector) – Professionals  All modes of application  Meta-SPC 3 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application with by spraying with a compression sprayer and rinsing with a compression sprayer (only use 5), wear chemical goggles and respiratory protective equipment against aerosols at minima APF 4  For application by spraying with a trigger spray, by mopping, wiping, scrubbing and pouring, wear chemical goggles  Professional bystander:  “Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.”  “Do not touch the surface until it is completely dried”  General public:  “Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray.”  “Do not touch the surface until it is rinsed and totally dried”  “Children should not be present during disinfection and until the surface is rinsed and dry” |
| Use 5 | Disinfection of hard surfaces (medical and non-medical sector) – Professionals  Application with a trigger spray  Application mopping/ wiping/ scrubbing  Application by pouring  Meta-SPC 1 and 7 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application with a trigger spray and rinsing, wear gloves, body protection, chemical goggles and only for application a respiratory protective equipment against aerosols  For application by mopping/scrubbing and rinsing with a mop, wear gloves, body protection and chemical goggles  “A mop/brush with handle has to be used to apply the diluted solution to avoid exposure”  “Do not immerse hands in the diluted solution”  For application by wiping/scrubbing and rinsing, wear gloves, body protection and chemical goggles  “Pour the solution directly on the surface and wipe with a cloth”  For application by pouring and rinsing, wear gloves, body protection and chemical goggles  “Avoid direct contact with the solution to be applied”  Professional bystander:  “Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.”  “Do not touch the surface until it is completely dried” (uses 2 and 3 meta-SPC 7)  General public:  “Do not be present in the treatment area during disinfection process by trigger spray.”  “Do not touch the surface until it is rinsed and totally dried”  “Children should not be present during disinfection and until the surface is rinsed and dry” |
| Disinfection of hard surfaces (medical and non-medical sector) – Professionals  Application with a compression sprayer and a Venturi sprayer  Meta-SPC 1 and 7 | **Not acceptable** |  |
| Disinfection of hard surfaces (medical and non-medical sector) – Professionals  All modes of application  Meta-SPC 2 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application by spraying with a compression sprayer and rinsing with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF 4  Professional bystander:  “Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user.”  General public:  “Do not be present in the treatment area during disinfection process by compression sprayer.” |
| Disinfection of hard surfaces (medical and non-medical sector) – Professionals  All modes of application  Meta-SPC 3 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application with by spraying with a compression sprayer and rinsing with a compression sprayer, wear chemical goggles and respiratory protective equipment against aerosols at minima APF 4  For application by spraying with a trigger spray, by mopping, wiping, scrubbing and pouring and rinsing, wear chemical goggles  Professional bystander:  “Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.”  “Do not touch the surface until it is completely dried”  General public:  “Do not be present in the treatment area during disinfection process by compression sprayer and trigger spray.”  “Do not touch the surface until it is rinsed and totally dried”  “Children should not be present during disinfection and until the surface is rinsed and dry” |
| Use 4 | Anti-lichen and anti-algae treatment of hard surface – Professionals  Meta-SPC 5 | **Not acceptable** |  |
| Use 6 | Disinfection of equipment/ materials by automatic spraying – Professionals  Meta-SPC 1 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading and post-application tasks, wear gloves, body protection and chemical goggles |
| Disinfection of equipment/ materials by automatic spraying – Professionals  Meta-SPC 2 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles |
| Disinfection of equipment/ materials by automatic spraying – Professionals  Meta-SPC 3 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For post-application tasks, wear chemical goggles |
| Use 7 | Disinfection of equipment/ materials by immersion/ soaking – Professionals  Meta-SPC 2 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles |
| Disinfection of equipment/ materials by immersion/ soaking – Professionals  Meta-SPC 3 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For application by immersion, wear chemical goggles |
| Uses 8/9 | Disinfection of hard surfaces in food and feed areas by CIP and Disinfection of inner surfaces in veterinary water systems – Professionals  Meta-SPC 1 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading and maintenance of circuit system, wear gloves, body protection and chemical goggles  For maintenance of dosing pumps, wear gloves, body protection, chemical goggles and respiratory protective equipment against aerosols |
| Disinfection of hard surfaces in food and feed areas by CIP and Disinfection of inner surfaces in veterinary water systems – Professionals  Meta-SPC 2 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading, wear gloves, body protection and chemical goggles  For maintenance of dosing pumps, wear gloves, body protection, chemical goggles and respiratory protective equipment against aerosols |
| Disinfection of hard surfaces in food and feed areas by CIP and Disinfection of inner surfaces in veterinary water systems – Professionals  Meta-SPC 3 | Acceptable,  with application of RMM and PPE | User:  For mixing and loading and maintenance of dosing pumps, wear gloves, body protection and chemical goggles  For maintenance of circuit system, wear chemical goggles |

**Non-Professional**

|  |  |  |  |
| --- | --- | --- | --- |
| **Overall conclusion on the risk assessment for human health from systemic and local exposure** | | | |
| **Use number** | **Use description** | **Conclusion** | **Set of RMMs** |
| Use 1 | Disinfection of sanitary installations – Non-professionals  Meta-SPC 4 and 6 | Acceptable,  with application of RMM | User:  “Washing on hands after use”  “Avoid contact with eyes” |
| Uses 2/5 | Disinfection of hard surfaces (non-medical sector) – Non-professionals  Application by mopping/ wiping/ scrubbing/ pouring  Meta-SPC 4 and 6 | Acceptable,  with application of RMM | User:  “Washing on hands after use”  “Avoid contact with eyes”  General public:  “Do not touch the surface until it is rinsed and totally dried”  “Children should not be present during disinfection and until the surface is rinsed and dry” |
| Disinfection of hard surfaces (non-medical sector) – Non-professionals  Application by spraying  Meta-SPC 4 and 6 | **Not acceptable** |  |

***Disinfection by-products exposure***

DBP can be formed during the different uses, however no data is available regarding the identity and content of these DBP and no guidance is also available for these uses. In this context no risk assessment can be performed.

***Dietary exposure***

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

**Sodium hypochlorite** is widely used for disinfection of surfaces and equipment in food and feed processing areas as well as for disinfection of drinking water, and thus, chlorate residues can be carried-over into food and feed during cleaning, washing and processing steps. Hence a dietary exposure assessment is presented below.

Residue definitions

**Nature of residue:**

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly (decomposition to physiological sodium and chloride). Hence, residue formation is assumed to be negligible for aqueous solutions of Na(OCl). Finally, no systemic assessment is required for substances such as Na(OCl) which act by a local mode of action only.

The BPC TOX-WG-IV-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for Na(OCl).

Furthermore, at EU level (WG TOX III-2016) it was finally discussed that only **chlorates** (ClO3-) is relevant for the dietary risk assessment. This relevant residue can be present in the BP as impurity and can be generated as Disinfection By Products (DBP) or degradation of the active ingredient in the biocidal product upon storage. Consequently, chlorates is a relevant compound to assess for food, feed and drinking water.

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Description of scenario** | **Type of use1** | **Subject of exposure2** |
| DRA-1 | Professional PT 4 use -  Indirect exposure via food | -Disinfection of hard surfaces in contact with food  - Disinfection of equipment/materials by automatic spraying in closed systems (tunnels)  - Disinfection of equipment/materials by immersion/soaking  - Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).  - Disinfection of inner surfaces in veterinary water systems | General public - Secondary  Exposure to food in contact with treated hard surfaces/equipment |
| DRA-2 | Non Professional PT 4 use -Indirect exposure via food | -Disinfection of hard surfaces in contact with food | General public Secondary  Exposure to food in contact with treated hard surfaces |

*Information of non-biocidal use of the active substance*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection products | Disinfectant – in irrigation water applied by watering tree – indoor use for mushroom crop.  Not approved as a PPP active substance. | ADI: 0.15 mg/kg bw/d  ARfD: not applicable  Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005. |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

**Scenario DRA-1**

With regards to professional intended PT 4 use, dietary exposure to available chlorine and chlorate in food was assessed and considered acceptable in the CAR[[8]](#footnote-9). This refers to the EFSA Scientific Opinion of the EFSA CONTAM Panel on “*Risks for public health related to the presence of chlorate in food*” (EFSA Journal 2015;13(6):4135) which includes a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data. The conclusion of this assessment remains valid for intended professional PT 4 uses:

*“Potential chlorate residues from the application of chlorine and hypochlorite in PTs 4 and 5 are considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 and PT5 uses of chlorine and hypochlorite. Since the EFSA Scientific Opinion on chlorate residues provides actual measured data for chlorate residues in food and an exhaustive exposure and risk assessment based on consumption data, the conclusions drawn in the EFSA Scientific Opinion are superior to any dietary risk assessment based on exposure models.”*

**Consequently, no dietary risk assessment is deemed necessary for the intended PT 4 professional uses.**

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

**Scenario DRA-2**

After non professional PT 4 use, general public may be exposed to chlorate residue by consumption of food that could have been in contact with hard surfaces treated.

Dietary exposure assessment has been performed according to ECHA guidance document[[9]](#footnote-10) for adults only. Indeed, as detailed in ECHA guidance document[[10]](#footnote-11), default value of 0.2 m2 for parameter “area in contact with food” is “*derived for adults; flexibility can be applied in regard to the value to be used for toddlers to allow for different or lower food consumption*”. Therefore, detailed scenario exposure is not representative of toddler food intake.

Exposure is only assessed for meta-SPC 6 as the content of chlorate in meta SPC 6 is higher than the one in meta SPC 4 (0.82% w/v vs 0.11% w/v).

| **Description of Scenario [DRA-2]** | | | |
| --- | --- | --- | --- |
|  | **Parameters** | **Value** | **Reference/remarks** |
| Tier 1 | Concentration of active chlorine in biocidal product (C) | 4.8% (meta SPC 6) | OXENA intended uses |
| In-use concentration of active chlorine (when a previous wash has been done) (C’) | 2.24 g/L (meta SPC 6) | OXENA intended uses |
| level of chlorates measured in the BP after storage (% w/v) (Ct) | 0.82% (meta SPC 6) | Stability data |
| Chlorate concentration at in-use concentration (C’’) | 382.67 mg/L | C’’= (C’/C)\*Ct |
| Water film thickness on treated surfaces | 0.002 cm | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017) (1) |
| Volume expected considering the water film thickness on treated surfaces (V) | 0.02 L/m² |  |
| Biocide residues on surface (mg a.s./m2) (Rsurface) | 7.65 mg/m² | Rsurface = C’’xV |
| Area in contact with food (A food contact) | 0.2 m2 | Guidance on the BPR : volume III P art B+C, Version 4.0 December 2017 - Default value for surface treatment, acute/ chronic exposure |
| Dietary Intake Fraction:  Acute/chronic exposure (D) | 1 / 0.5 | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 |
| Default Body weight (kg)adults (bw) | 60 kg | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 |
| Mass transfer efficiency (TF) | 1 | Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 - Default value (worst case) |
|  | Remaining residues on treated surfaces after a rinsing step Tier I (RF) | 100% | Default rinsing factor |
| Tier 2 | Remaining residues on treated surfaces after a rinsing step Tier II (RF) | 10% | Default rinsing factor |

1. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017

**Calculations for Scenario [DRA-2]**

Following equation has been used to estimate adult, chronic/acute consumer exposure in both Tier I and Tier II:

Expcons = Rsurface x Afood contact x TF x D x RF ÷ bw

|  |  |  |  |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier** | **Exposure** | **Adult** |
| Scenario [DRA-2] | Tier 1 | Estimation of consumer exposure via food (acute exposure)  (mg/kg bw) | 0.0255 |
| Estimation of consumer exposure via food (chronic exposure)  (mg/kg bw) | 0.0128 |
| Scenario [DRA-2] | Tier 2 | Estimation of consumer exposure via food (acute exposure)  (mg/kg bw) | 0.0026 |
| Estimation of consumer exposure via food (chronic exposure)  (mg/kg bw) | 0.0013 |

**Conclusion**

For non-professional PT 4 uses, dietary exposure assessment has been performed according ECHA guidance document[[11]](#footnote-12) for adults.

**Maximum residue limits or equivalent**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| Drinking water limit – chlorate | WHO, 2005 WHO/SDE/WSH/05.08/86[[12]](#footnote-13) | Drinking water | 0.7 mg/L |
| Drinking water limit – chlorate | Water Directive  Proposed limit (EC 2020[[13]](#footnote-14)) | Drinking water except for disinfection method | 0.25 mg/L |
| MRL chlorate - Reg. (EU) 2020/749 | MRL fixed based on monitoring data and target sampling on Food commodities | Raw food commodities  plant and animal matrices | From 0.05 to 0.7 mg/kg |

***Risk for consumers via residues in food***

For the intended PT 4 professional uses, no dietary risk assessment is deemed necessary. For intended PT 4 non professional use, dietary risk assessment has been performed according ECHA guidance document[[14]](#footnote-15) for adults and results are detailed below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Risk for consumers via residues in food*** | | | | | |
| **Scenario DRA 2: Non professional PT 4 use** | | | | | |
|  | | **Dietary exposure** (mg/kg bw/d) | | **Dietary Risk** % of ADI (0.003 mg/kg b.w./d) or ARfD (0.036 mg/kg b.w.) | |
|  | | **Tier I** | **Tier II** | **Tier I** | **Tier II** |
| Adult (chronic) | 0.0128 | | 0.0013 | 425.2 | 42.5 |
| Adult (acute) | 0.0255 | | 0.0026 | 70.9 | 7.1 |

**Conclusion**

For non-professional PT 4 uses:

* in Tier 1: Indirect exposure via food is above ADI and ARfD
* in Tier 2: Indirect exposure via food is below toxicological reference values (both ADI and ARfD)

According to ECHA guidance, rinsing step is not likely to be done by non professional users. EU Commission’s action plan for chlorate consists, amongst other proposals, to recommend good food hygiene practices in order to reduce chlorate coming from chlorinated disinfectants[[15]](#footnote-16). Therefore eCA is of the opinion that this RMM is necessary for OXENA Family in order to reduce chlorate consumer exposure.

As a conclusion, no concern for general public from indirect exposure to either available chlorine or chlorate in food is observed when a rinsing of treated surfaces occurs.

***Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product***

Not relevant.

### Risk assessment for animal health

Uses 2, 3 and 5: Disinfection of hard surfaces (medical and non medical sector)

Animals may be exposed to treated surfaces when re-entering the housing. Inhalation and dermal exposure of animals to active chlorine is considered covered by the assessment performed for the general public (secondary exposure).

Similar RMMs set for human secondary exposure are therefore required to avoid animal exposure:

Meta-SPC 1, 3, 4 and 6, for all modes of application:

* Animals should not be present during disinfection and until the surface is rinsed and dry

Meta-SPC 2, only for application by spraying with a compression sprayer:

* Animals should not be present in the treatment area during disinfection process by compression sprayer.

As the risk is not acceptable for Use 4: anti-lichen and anti-algae treatment of hard surfaces, exposure to general public and pets is not relevant.

For uses 6, 7, 8 and 9, no exposure to general public, and therefore animals, is expected.

### Risk assessment for the environment

Products of the Oxena family are PT2 and 4 disinfectants. They are applied for:

* PT2 disinfection of sanitary installations (e.g toilet bowls, drains, sink): The liquid formulas are applied to surfaces by pouring (Meta SPC 2, 3, 4, 6, 7). Product emissions occur to the STP.
* PT2 disinfection of hard surfaces (non-medical sector): The products are used by spraying, wiping, pouring, mopping or scrubbing (Meta SPC 2, 3, 4, 6, 7). Product emissions occur to the STP.
* PT2 disinfection of hard surfaces (medical-sector): The products are used by spraying, wiping, pouring, mopping or scrubbing (Meta SPC 2, 3). Product emissions occur to the STP
* PT2 disinfection of equipment/materials by immersion/soaking: The producst are used by immersion (Meta-SPC 2, 3). Products emissions occur to the STP.
* PT2 Anti-lichen and anti-algae treatment of hard surfaces: The products are used by spraying to surfaces such as wall, floor, roof etc… (Meta-SPC 5). Product emissions

occur to the STP, surface water and soil.

* PT 2 & 4 disinfection of equipment/materials by automatic spraying in closed systems (tunnels): The products are usedby spraying (Meta-SPC1, 2, 3). Product emissions occur to the STP.
* PT4 disinfection of hard surfaces in contact with food: The products are used by spraying, wiping, pouring, mopping or scrubbing (Meta-SPC 1, 2, 3, 4, 6, 7). Product emissions occur to the STP.
* PT4 disinfection of equipment/materials by immersion/soaking: The products are used by immersion (Meta-SPC 2, 3). Product emissions occur to the STP.
* PT4 disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion exchangers and tanks of filling machines or similar): The products are used by pouring in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP) (Meta-SPC 1, 2, 3). Product emissions occur to the STP.
* PT 4 disinfection of inner surfaces in veterinary water systems: The products are used by pouring (Meta-SPC 1, 2). Product emissions occur to the STP.

Active substance

The active substance within the product family is active chlorine released from sodium hypochlorite (CAS: 7681-52-9). According to the active substance’s assessment report (2017), hypochlorous acid (HClO) is in equilibrium with the hypochlorite ion (ClO-) and chlorine (Cl2). The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is predominant, and at pH values higher than 10, the only species present is the hypochlorite ion, see figure below.



The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or available chlorine. For the chemical reactivity in aqueous solution with the same active chlorine concentrations and the same pH conditions, it is irrelevant whether active chlorine is generated from either chlorine gas, calcium hypochlorite or sodium hypochlorite. Therefore, all studies investigating hypochlorite aqueous solutions can be used for evaluation and assessment of active chlorine released from any of the three substances.

TRC (total residual chlorine) is a measurement of both Free Available Chlorine or FAC (in practice, only HClO and OCl─ are usually present because Cl2 is formed only at pH < 4) and combined chlorine (such as chloramines). It is difficult to separate the contribution to toxicity of FAC from that of the combined chlorine species. For studies where the percentage of FAC in TRC was measured, the toxicity endpoints were expressed as FAC/L as well.

Available chlorine (or free chlorine) is expressed as equivalent content of Cl2 (AR, 2017). The active chlorine equivalent content is:

* 1 g of sodium hypochlorite is equivalent to 0.953 g active chlorine (MWCl2 / MWNaOCl = 71/74.5)
* or 1 g active chlorine equivalent to 1.05 g sodium hypochlorite (MWNaOCl / MWCl2 = 74.5 / 71).

Substance of Concern

One substance of concern has been identified for the environment: Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS n° 308062-28-4) and a complete risk assessment has been performed (see confidential annex for further details on the identification). This substance of concern is relevant for meta-SPC 1 only.

Chlorate formation during storage

The maximal sodium chlorate content at the end of storage exceeds the reference specification for the Meta-SPC 1, 2, 5, 6 & 7 (ranging from 9.4 to 49% w/w between the different Meta-SPC, while the limit is 5.4% w/w (refer to section 2.2.2). Consequently, a risk assessment of chlorate formed during storage is needed for these Meta-SPC.

No harmonized endpoints are actually available for chlorate. As agreed during the WG-I-2020-Part B meeting, considering that chlorate (EC50 = 10 mg/L) is less toxic than the active substance (EC50 = 0.023 mg free available chlorine/L), it can be assessed qualitatively for all the environmental compartments including groundwater.

Chlorate is a substance of concern in relation to human health. Then, a semi qualitative assessment of chlorate in groundwater and surface water intended for the abstraction of drinking water have been performed (worst case assessment based on the maximal chlorate concentration, *i.e.* at the end of the storage period, as proposed for the HH assessment).

Disinfection by-products (DBPs)

An environmental risk assessment of DBPs has been provided by the applicant. A summary of the evaluation is given in Annex 3.7. The risk assessment is still under development and will be amended as agreement on PNEC values and exposure concentrations of DBPs are agreed at Working Group level. Indeed, a harmonization of the environmental risk assessment for DBPs is currently under investigation at EU level. Consequently, and according to the WG-I-2020 Part B meeting agreements, any conclusion on the risk of DBPs for the environment cannot be drawn for the time being.

#### Effects assessment on the environment

According to the active substance’s assessment report (2017), short and long term toxicity data from literature are available for fish, invertebrates, algae and micro-organisms, resulting from flow-through or static tests. Most tests with a static test design result in a factor of 100-500 higher end-points (NOEC, LC50) than studies performed according to a flow-through design. Due to very fast hypochlorite decay, a static test system is continuously exposed to the same hypochlorite concentration. When data from literature were considered not valid or incomplete for the risk assessment, new toxicity laboratory studies were performed and included in the CAR.

No new environmental studies have been conducted on the products. All agreed endpoints have been taken from the final Assessment Report Active substance released from sodium hypochlorite in water (2017). The predicted no effect concentration values (PNEC) are summarised in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PNEC** | **Lowest endpoint** | **AF** | **PNEC** | **Test/species** |
| **Free available chlorine (FAC)** | | | | |
| STP | NOEC: 41.1 mg/L | 10 | 4.11 mg FAC/L | Respiration inhibition test |
| fresh water | NOEC: 2.1 µg/L | 50 | 0.042 FAC µg/L | Algae |
| sediment | - | - | 0.045 μg FAC/kg wwt | Equilibrium partitioning from aquatic data using a theoretical Koc of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV. |
| soil | - | - | 0.015 μg FAC/kg wwt |
| groundwater | Reference value for groundwater = 0.1 μg/L | | | |
| atmosphere | At environmental pH (6.5-8.5) half of the active chlorine is available as the non-volatile hypochlorite ion; half as hypochlorous acid with a Henry’s law constant as 0.11 Pa m³/mol. Hence, the concentration in air will be very low and the air is not an environmental compartment of concern. | | | |
| birds | No data available for birds and mammals as primary and secondary poisoning is not considered relevant. | | | |

Concerning the assessment of the substance of concern identified for the environment (Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides; CAS n° 308062-28-4), the PNECS have been taken from the REACH registration dossier:

<https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15191>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PNEC** | **Lowest endpoint** | **AF** | **PNEC** | **Test/species** |
| **Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides** | | | | |
| STP | EC10 : 24 mg/L | 1 | 24.0 mg/L | Two reliable studies are available. In the key study, *Pseudomonas putida* were exposed to nominal concentrations of 0, 50, 100, 600, 1000, 10000 or 100000 mg/L of C12 -14 AO for 18 hours in a Bringmann-Kuehn test [Kolvenbach M (1990)].  The EC10 was based on reduction in growth rate. |
| fresh water | NOEC: 0.067 mg/L | 2 | 0.034 mg/L | Algae is the most sensitive aquatic species. The 72-h ErC50 for algae of 0.143 mg AO/L is calculated as the geometric mean of the results from four reliable studies performed on *Pseudokirchnerella subcapitata* which appears to be the most sensitive algal species based on the available data.  The 28-d NOEC of 0.067 mg AO/L is derived from a periphyton microcosm study in which more than 110 taxa of algae were exposed to the substance (that justifies an AF of 2 according to the BPR guidance). |
| sediment | - | - | 1.32 mg/kg wwt | Equilibrium partitioning from aquatic data using a theoretical Koc of 1746.4 L/kg. Calculated according to the Guidance part B, vol. IV.  The PNEC soil is considered to be a twa value as PNEC water is based on measured values over all duration of the assay. |
| soil | - | - | 1.05 mg/kg wwt |
| ground  water | Reference value for groundwater = 0.1 μg/L | | | |
| atmo  sphere | The concentration in air will be very low and the air is not an environmental compartment of concern. | | | |
| birds | Primary and secondary poisoning are not considered relevant. | | | |

Please note that a justification on the AF is presented in the Ecotoxicological summary of the registration dossier. In absence of other data available, these PNECs are taken into account for the environmental risk assessment.

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

All relevant data can be extrapolated from the active substance Active chlorine released from sodium hypochlorite (AR, 2017). Testing of the product is not required.

The products contains classified ingredients other than the active substance (active chlorine released from sodium hypochlorite). However, the classification of the co-formulants included in the different META-SPC does not lead to additional classification (refer to the confidential PAR for detail).

Thus, the environmental hazard classification of the products is driven by the active substance classified as **Aquatic Acute 1, H400 (M=10), Aquatic chronic 1, H410 (M=1)** according to the Regulation (EC) No 1272/2008 (CLP). The classification **H400, H411** applies to all the META-SPC within the family considering a concentration of the active substance in products between 25 and 2.5% except for meta-SPC 7 which is classified **H412**.

***Further Ecotoxicological studies***

No further ecotoxicological studies have been conducted on active chlorine or the active chlorine releasing product supported in this document.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No new data is available for the Oxena family.

***Supervised trials to assess risks to non-target organisms under field conditions***

No new data is available for the Oxena family.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No new data is available for the Oxena family.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No new data is available for the Oxena family.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

See Fate and distribution in exposed environmental compartments.

***Further studies on fate and behaviour in the environment (ADS)***

No new data is available for the Oxena family.

***Leaching behaviour (ADS)***

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for the intended uses within PT1-5.

***Testing for distribution and dissipation in soil (ADS)***

No new data is available for the Oxena family.

***Testing for distribution and dissipation in water and sediment (ADS)***

No new data is available for the Oxena family.

***Testing for distribution and dissipation in air (ADS)***

No new data is available for the Oxena family.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

No new data is available for the Oxena family.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

No new data is available for the Oxena family.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | * Scenario 1a – Disinfection in institutional areas – Lavatory * Scenario 1b – Disinfection in institutional areas – General purpose * Scenario 2 – Disinfection in industrial premises * Scenario 3 - Disinfection of rooms, furniture and objects (medical sector) * Scenario 4 – Disinfection of equipment and instruments by immersion in medical sector * Scenario 5 – Anti-lichen and anti-algae treatment of hard surfaces |
| ESD(s) used | * Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), P. van der Poel, 2001. * ESD for PT 2: Emission Scenarios for private and public health area disinfectants and other biocidal products (RIVM, 2001) * Emission scenario document for biocides used as masonry preservatives. (product type 10) * TAB ENV v2 ENV-55 |
| Approach | * Scenario 1: Tonnage and Average consumption * Scenario 2: Average consumption * Scenario 3: Tonnage and Average consumption * Scenario 4: Average consumption * Scenario 5: Average consumption |
| Distribution in the environment | Estimated according to :   * Guidance on the Biocidal Products Regulation, Vol. IV. Env., Parts B+C, Version 2.0 (October 2017). * Assessment report: Active chlorine released from sodium hypochlorite, Product-type 2, January 2017. * Technical Agreements for Biocides, August 2017. |
| Groundwater simulation | No |
| Confidential Annexes | Yes |
| Life cycle steps assessed | Product use |
| Remarks | - |
| Assessed PT | PT 4 |
| Assessed scenarios | * Scenario 1 – Disinfection of hard surfaces, in contact with food: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) IHO (2006) * Scenario 2 – Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries * Scenario 3 – Disinfection of milking parlour systems * Scenario 4 – Disinfection of equipment and instruments by immersion |
| ESD(s) used | [ESD for PT 4: Emission scenarios for Disinfectants used in food and feed areas (JRC Scientific and Technical Reports, 2011)](https://echa.europa.eu/documents/10162/16908203/pt4_food_disinfectants_en.pdf/e264b048-f2bf-4366-adcc-3b4f5b5d6f9c) |
| Approach | * Scenario 1: Average consumption * Scenario 2: Average consumption * Scenario 3: Average consumption * Scenario 4: Average consumption |
| Distribution in the environment | Estimated according to :   * Guidance on the Biocidal Products Regulation, Vol. IV. Env., Parts B+C, Version 2.0 (October 2017). * Assessment report: Active chlorine released from sodium hypochlorite, Product-type 2, January 2017. * Technical Agreements for Biocides, August 2017. |
| Groundwater simulation | Yes |
| Confidential Annexes | No |
| Life cycle steps assessed | Product use |
| Remarks | - |

The claimed uses and the scenarios covering each of them are presented in the following table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Meta-SPC** | **PT** | **Description of use** | **Covered by** |
| **2, 3, 4 6, 7** | **2** | Use 1: Disinfection of sanitary installations (e.g toilet bowls, drain, sink) | PT2- Scenario 1a & 1b:  Disinfection in institutional areas – Lavatory/General purpose |
| **2, 3, 4, 6, 7** | **2** | Use 2: Disinfection of hard surfaces (non-medical sector) | PT2- Scenario 2: Disinfection in industrial areas (pro) + PT2- Scenario 1:  Disinfection in institutional areas (non-pro) |
| **2, 3** | **2** | Use 3: Disinfection of hard surfaces (medical sector) | PT2- Scenario 3: Disinfection of rooms, furniture and objects |
| **2, 3** | **2** | Use 7: Disinfection of equipment/materials by immersion/soaking | PT2- Scenario 4: Disinfection of equipment and instruments by immersion in medical sector |
| **5** | **2** | Use 4: Anti-lichen and anti-algae treatment of hard surfaces | PT2- Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces |
| **1, 2, 3, 4, 6, 7** | **4** | Use 5: Disinfection of hard surfaces in contact with food | PT4- Scenario 2 : Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries |
| **1, 2, 3** | **2/4** | Use 6: Disinfection of equipment/materials by automatic spraying in closed systems (tunnels) | PT4- Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) |
| **2, 3** | **4** | Use 7: Disinfection of equipment/materials by immersion/soaking | PT4- Scenario 4: Disinfection of equipment and instruments by immersion |
| **1, 2, 3** | **4** | Use 8: Disinfection of hard surfaces (e.g pipelines, tubes, separative membranes/ion exchangers and tanks of filling machines or similar) by CIP | PT4- Scenario 3: Disinfection of milking parlour systems |
| **1, 2** | **4** | Use 9: Disinfection of inner surfaces in veterinary water systems | PT4- Scenario 1: Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) |

**Emission estimation**

The calculated daily emission of active chlorine to the sewage treatment plant does not take into account a degradation of the active substance in the sewer system. Standard biodegradability testing in the STP is not applicable to inorganic substances such as NaOCl. However, the active substance assessment reports indicates that “Active chlorine is highly reactive: it reacts rapidly with organic matter in the sewer, STP, surface water, and soil. Where organic and nitrogenous materials are present, it acts as a highly reactive oxidizing agent. After reaction with organic matter, most (≈99%) of the active chlorine is converted to inorganic chloride. The kinetic model of Vandepitte and Schowanek shows that hypochlorite is eliminated during transport in the sewer within the first minutes. The abundance of reaction partners allows a very quick reaction. The [free chlorine] concentration estimated at the end of the sewer drops below 1 x 10-32 µg/L.

Degradation of hypochlorite in the sewer system was therefore considered. Based on the assessment report of active chlorine released from sodium hypochlorite, the DT50 is 56 seconds at 12°C for hypochlorite in the sewer system. This value is used for the emission estimation. No degradation was considered for chlorates.

A sewer residence time of 1h is proposed a default value in the ESD, based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

This degradation is taken into account in all relevant uses.

**PT2 scenarios**

Both approaches, tonnage-based and average consumption are presented in the assessment for PT02 uses. The tonnage-based scenario is available in section 3.7.1.1 of confidential annexes.

##### PT2 - Scenario 1a: Disinfection of institutional areas – Lavatory (Meta-SPC 2, 3, 4, 6, 7) covering use 1 - Disinfection of sanitary installations (medical and non medical sector) and use 2 – Disinfection of hard surfaces (non medical sector, non-professional applications)

Local emission due to disinfection of lavatory and surfaces were calculated using ESD for PT2 Disinfection in institutional areas (RIVM, 2011). This scenario covers the use Disinfection of sanitary installations, specifically toilet bowls, and Disinfection of hard surfaces (non medical sector, non-professional applications). This assessment covers pouring (worst case in term of concentrations).

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Meta-SPC 2 | | Meta-SPC 3 | Meta-SPC 4 | Meta-SPC 6 | | Meta-SPC 7  (gel) | |
| Substances | Active chlorine | Chlorate | Active chlorine | Active chlorine | Active chlorine | Chlorate | Active chlorine | Chlorate |
| Concentration of substance | 12.5  (% w/w) | 3.2  (% w/v) | 2.6  (% w/w) | 2.6  (% w/w) | 4.8  (% w/w) | 0.82  (% w/v) | 2.2  (% w/w) | 0.15  (% w/v) |
| Dilution factor | 0.04 | | 0.177 | 0.08 | 0.044 | | - | |
| Density | 1.2106 | | 1.0521 | 1.03 | 1.075 | | 1.1 | |
| Concentration in working solution (g/L) | 6.053 | 1.28 | 4.84 | 2.1 | 2.3 | 0.36 | **24.2** | **1.50** |

The products of Meta-SPC 7 are used pure when disinfecting the toilet bowls. Therefore this Meta-SPC is considered as the worst-case and will be used for the calculations for the active substance and for chlorates.

The average consumption is presented below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | |
| **Input** | **Value** | | **Unit** | **Remarks** | |
| *Scenario 1 – Average consumption, Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on average consumption (ESD PT2, 2001, p.10)* | | | | | |
| Number of inhabitants feeding one STP [*Nlocal*] | 10 000 | | - | Default value (ESD PT2, 2001) | |
| Fraction released to waste water [*Fwater*] | 1 | | - | Default value (ESD PT2, 2001) | |
| Substance in product [*Cproduct*]  Active chlorine  Chlorate | 2.42E+01  1.50E+00 | | g/l |  | |
| Consumption per capita [*Qproduct*]:  - Lavatory | 0.002 | | l/cap.d | Default value for general purposes (ESD PT2, 2001) | |
| Penetration factor of disinfectant [*Fpenetr*] | 0.5 | | - | Default value (TAB, 2017) | |
| **Output** | | | | | |
| Calculation:  Elocalwater = Nlocal \* Qproduct \* Cproduct \* Fpenetr \* Fwater | | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | | 2.42E-01 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | | 1.50E-02 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 1.08E-20 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 - Scenario 1b: Disinfection of institutional areas - Lavatory (Meta-SPC 2, 3, 4, 6, 7) covering use 1 - Disinfection of sanitary installations (medical and non medical sector) and use 2 – Disinfection of hard surfaces (non medical sector, non-professional applications)

Local emission due to disinfection of lavatory and surfaces were calculated using ESD for PT2 Disinfection in institutional areas (RIVM, 2011). This scenario covers the use Disinfection of sanitary installations (e.g drains, sink) and Disinfection of surface application and pouring (worst case in term of concentrations).

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Meta-SPC 2 | | Meta-SPC 3 | Meta-SPC 4 | Meta-SPC 6 | | Meta-SPC 7  (gel) | |
| Substances | Active chlorine | Chlorate | Active chlorine | Active chlorine | Active chlorine | Chlorate | Active chlorine | Chlorate |
| Concentration of substance | 12.5  (% w/w) | 3.2  (% w/v) | 2.6  (% w/w) | 2.6  (% w/w) | 4.8  (% w/w) | 0.82  (% w/v) | 2.2  (% w/w) | 0.15  (% w/v) |
| Dilution factor | 0.04 | | 0.177 | 0.08 | 0.044 | | 0.07 | |
| Density | 1.2106 | | 1.0521 | 1.03 | 1.075 | | 1.1 | |
| Concentration in working solution (g/L) | **6.053** | **1.28** | 4.84 | 2.1 | 2.3 | 0.36 | 1.69 | 0.11 |

The Meta-SPC 2 is considered as the worst-case and will be used for the calculations for the active substance and for chlorates.

The average consumption is presented below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | | |
| **Input** | **Value** | | **Unit** | **Remarks** | |
| *Scenario 1 – Average consumption, Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on average consumption (ESD PT2, 2001, p.10)* | | | | | |
| Number of inhabitants feeding one STP [*Nlocal*] | 10 000 | | - | Default value (ESD PT2, 2001) | |
| Fraction released to waste water [*Fwater*] | 1 | | - | Default value (ESD PT2, 2001) | |
| Substance in product [*Cproduct*]  Active chlorine  Chlorate | 6.053E+00  1.28E+00 | | g/l |  | |
| Consumption per capita [*Qproduct*]:  - Lavatory | 0.005 | | l/cap.d | Default value for general purposes (ESD PT2, 2001) | |
| Penetration factor of disinfectant [*Fpenetr*] | 0.5 | | - | Default value (TAB, 2017) | |
| **Output** | | | | | |
| Calculation:  Elocalwater = Nlocal \* Qproduct \* Cproduct \* Fpenetr \* Fwater | | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | | 1.51E-01 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | | 3.20E-02 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater =6.73E-21 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 - Scenario 2: Disinfection of industrial premises (Meta-SPC 2, 3, 7) covering use 2 - Disinfection of hard surfaces (non medical sector, professional applications)

Local emission due to disinfection of industrial areas were calculated using ESD for PT2 Disinfection in industrial premises (RIVM, 2011). This scenario applies to disinfection of a wide range of surfaces: small surfaces such as furniture and bigger surfaces such as rooms, walls or floors. Industrial premises are considered as local emission sources which release their wastewater to a local STP. It covers the use “Disinfection of hard surfaces (non medical sector, professional applications)”.

The scenario is based on the concentration of the active substance and volume applied on a surface: an application rate of 0.1 L/m² (based on Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019, in case of absence of more specific information) was considered for the assessment. A surface area of 1000 m² was assessed as it represents a worst-case according to the ESD.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Meta-SPC 2 | | Meta-SPC 3 | Meta-SPC 7  (gel) | |
| Substances | Active chlorine | Chlorate | Active chlorine | Active chlorine | Chlorate |
| Concentration of substance | 12.5  (% w/w) | 3.2  (% w/v) | 2.6  (% w/w) | 2.2  (% w/w) | 0.15  (% w/v) |
| Dilution factor | 0.040 | | 0.177 | 0.07 | |
| Density | 1.2106 | | 1.0521 | 1.1 | |
| Concentration in working solution (g/L) | **6.053** | **1.28** | 4.84 | 1.69 | 0.11 |

The Meta-SPC 2 is considered as the worst-case and will be used for the calculations for the active substance and chlorates.

Input parameters for the emission scenario - Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Application rate of biocidal product | l/m² | Vform | S | 0.1 |  |
| Concentration of :  Active chlorine  Chlorate | g/l | Cform | S | 6.053E+00  1.28E+00 |  |
| Surface area to be disinfected | m² | AREAsurface | D | 1000 |  |
| Number of applications per day | d-1 | Nappl | D | 1 |  |
| Fraction of substance disintegrated during or after application (before release to the sewage system) | [-] | Fdis | D | 0 |  |
| Fraction released to wastewater | [-] | Fwater | D | 1 |  |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Vform \* Cform \* AREAsurface \* Nappl \* (1-Fdis) \* Fwater / 1000 | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 6.05E-01 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.28E-01 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 2.69E-20 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 - Scenario 3: Disinfection of rooms, furniture and objects (medical sector) (Meta-SPC 2, 3) covering use 3 - Disinfection of hard surfaces (medical sector)

Local emission due to disinfection surfaces in medical sector was calculated using ESD for PT2 by Van der Poel (2001). This scenario covers disinfection in primary health care areas and hospital sector. It covers the use “Disinfection of hard surfaces (medical sector)” and Sanitary installation (medical sector)

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Meta-SPC 2 | | Meta-SPC 3 |
| Substances | Active chlorine | Chlorate | Active chlorine |
| Concentration of substance | 9.6 (% w/w) | 3.2 (%w/v) | 2.6 (% w/w) |
| Dilution factor | 0.048 | | 0.177 |
| Density | 1.15 | | 1.0521 |
| Concentration in working solution (g/L) | **5.3** | **1.54** | 4.84 |

The Meta-SPC 2 is considered as the worst-case and will be used for the calculations for the active substance.

The average consumption is presented below:

Input parameters for the emission scenario - Disinfection of hard surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Fractions released to waste water:  Sanitary purposes  Brushes | - | Fsan,water  Fobj,water | D | 0.55  0.95 |  |
|  |
| Concentration at which active substance is used:  Active chlorine:  Sanitary purposes  Brushes  Chlorate:  Sanitary purposes  Brushes | g/l | Csan  Cobj | S | 5.30E+00  5.30E+00  1.54E+00  1.54E+00 |  |
| Amount of water with active substance:  Sanitary purposes  Brushes | l.d-1 | Qwater\_san  Qwater\_obj | D | 25  25 |  |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Qwater\_san\*Csan\*Fsan,water+Qwater\_obj\*Cobj\*Fobj,water (sanitary purposes + brush) | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.99E-01 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 5.78E-02 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 8.83E-21 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 - Scenario 4: Disinfection of equipment and instruments by immersion (Meta-SPC 2 & 3)

According to the TAB ENV v2.0, ENV-45, a scenario has been proposed for the disinfection of medical equipment by dipping. This scenario has thus been used in the following assessment, applying the default values agreed at WG-I-2015. It is assumed that 30 dipping baths per day (default value from the TAB) is a worst-case value for both uses.

It covers the use “Disinfection of equipment/materials by immersion/soaking.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Meta-SPC 2 | | Meta-SPC 3 |
| Substances | Active chlorine | Chlorate | Active chlorine |
| Concentration of substance | 12.5 (% w/w) | 3.2 (% w/v) | 2.6 (% w/w) |
| Dilution factor | 0.040 | | 0.177 |
| Density | 1.2106 | | 1.0521 |
| Concentration in working solution (g/L) | **6.053** | **1.28** | 4.84 |

The Meta-SPC 2 is considered as the worst-case and will be used for the calculations for the active substance.

There is no assessment of chlorate needed for meta-SPC 3 and thus the dose of chlorates in meta-SPC 2 will be used.

Input parameters for the emission scenario - Disinfection of equipment and instruments by immersion:

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| Concentration of :  Active chlorine  Chlorate  [Cdisinf] | 6.053  1.28 | g/L |  |
| Volume of solution in dipping bath [Qdipping\_bath] | 0.01 | m3 | D |
| Maximum number of dipping bath per day [Ndipping\_bath] | 30 | d-1 | D |
| Fraction released to wastewater [Fwater] | 1 | - | D |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Cdisinf • Qdipping\_bath • Fwater • Ndipping\_bath • 10 | | | | |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.82E+00 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 3.84E-01 | As Chlorate |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 8.07E-20kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT2 - Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces (Meta-SPC 5)

There is no substance of concern in Meta-SPC 5.

There is no existing Emission Scenario Documents (ESD) for PT2 covering use of an algaecide on construction materials; therefore, the assessment of environmental emissions for OXENA FAMILY products has been conducted using several guidance documents. The assessment is based on models simulating spray application on hard surfaces likely to be treated by non-professionals from ESD for PT10 (Emission scenario document for biocides used as masonry preservatives, EUBEES 2002) and ESD for Product Type 8 (Revised Emission Scenario Document for Wood Preservatives, OECD 2013).

Estimation of environmental concentrations due to use and service life of OXENA FAMILY was conducted considering two hard surface models:

* House (walls and roof) from ESD PT10
* Bridge over pond, from ESD PT8

Considering the physico-chemical properties of the active substance, a service life is not relevant as it will react very rapidly with the organic matter on the treated surfaces and thus this service-life phase is not assessed in this dossier.

Moreover it was decided at WGI2020 that the only relevant pathway of a quantitative assessment was surface water in case of direct release. Therefore, active chlorine exposure and risk assessment will be proposed only for the bridge over pond scenario.

**House scenario**

According to ESD for PT10, assessment of emissions has been performed for two types of houses: house in rural area for which all loses of product during application go to local soil and house in a city for which all loses go to rain water.

Based on the ESD and the supplementing document “The assessment of direct emission to surface water in urban areas”, products applied on facades or roofs are subject to leaching during rain events. However as a worst-case, we considered that 100% of the product applied is released directly to the STP/separate sewer system, or the adjacent soil.

|  |  |
| --- | --- |
| **Scenario** | **Receiving compartments** |
| House in a city | Surface water, Soil, Sediment |
| House in the countryside | Soil adjacent to application area |

Calculations were done for an area of 270 m² (145 m² roof + 125 m² walls) according to the model house proposed in OECD (2002) (used in ESD PT10).

Concerning the soil distant to a treated horizontal surface, the risk can be considered to be covered by the assessment of vertical surfaces as the spray drift will be lower. Regarding soil adjacent to a treated horizontal surface, run-off is more likely and cannot be mitigated.

For vertical surfaces both facade and roof were considered for the risk assessment. Compared to a horizontal surface with a smaller treated area releasing product to the adjacent soil compartment, this assessment can be considered as a worst case situation.

**Emissions during application (considering a total release of the whole applied product):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** |
| Fraction of substance in the product:  Active chlorine  Chlorate | Fform | (-) | 0.0678  0.0059 | S – considering a product density of 1.13 |
| Volume of product applied on area | V form | l.m-2 | 0.1 | S – intended application rate |
| Application interval of the product | Applic\_interval | years | 1 | S – intended |
| Number of houses in a city | Nhouse | (-) | 4000 | D |
| Fraction of houses on which an algaecide/disinfectant is applied (considering a market share = 1.0) | fhouse | (-) | 0.5 | D (AHEE-4) |
| Number of houses treated per day in the city scenario | nhouse\_applic\_city | d-1 | 6 | O (TAB v2.0 ENV119) |
| Number of houses treated in the countryside scenario | nhouse\_applic\_countryside | (-) | 1 | D |
| Treated area of a façade | AREAfaçade | m2 | 125 | D |
| Treated area of a roof | AREAroof | m2 | 145 | D |
| Density of the product | RHOform | kg/m3 | 1000 | D |
| Fraction of product lost during application (covering post-application releases | Fspray | (-) | 1 | S (as a worst-case) |

Model calculation for spray application (considering a release of the total applied quantity as a worst case) for the rural area:

Local emission of active substance during application considering that all the product is lost during application:

*Elocal spray = (AREAfaçade + AREAroof) x V form x C form x Fspray x E-3*

**House in the countryside – Emissions to local soil due to direct emissions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emissions to local soil (kg.kgwwt-1)** | |
|  | | | **Active chlorine** | **Chlorate** |
| ESD PT10 House in the countryside | Elocal soil(d) | Soil adjacent to treated surface | 1.83E+00 | 1.59E-01 |
| Elocal soil(a) |

Model calculation for spray application (considering a release of the total applied quantity as a worst case) for the urban area:

Local emission of active substance during application (separate sewer systems)

*Elocal water = nhouses\_applic\_city\*Elocalspray*

**House in the urban area – Emissions to STP or separate sewer systems**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Emission rate to rain water (kg.d-1)** | |
|  |  |  | Active chlorine | Chlorate |
| ESD PT10 House in a city | Elocal water | Rain water (connected to the sewer system) | 1.10E+01 | 9.56E-01 |

It was decided at WGI2020 that the only relevant pathway justifying a quantitative assessment of active chlorine was surface water in case of direct release. Therefore, active chlorine exposure and risk assessment for direct release to soil are not presented.

Chlorate is a substance of concern in relation to human health. Then, a semi qualitative assessment of chlorate in groundwater and surface water intended for the abstraction of drinking water have been performed (worst case assessment based on the maximal chlorate concentration, *i.e.* at the end of the storage period, as proposed for the HH assessment).

PEC groundwater for chlorates (rural area):

Concerning the direct release to soil in the countryside, the PECgw for chlorate has been calculated from the PECsoil considering 1 hectare as follow:

PECsoil/ha = Elocalsoil\*nhouse/Vsoil = **3.00E-01 mg/kg wwt**

* nhouse = 16 houses per hectare (TAB v2.0 ENV 98)
* The soil volume of 1 hectare is : Vsoil= 10000\*0.5\*1700 = 8.5E+06 kg soil/ha

With : RHOsoil = 1700kg/m3

Depth: 0.5 m

We can thus deduce a PECgw/ha :

PECgw/ha = PECsoil \* RHOsoil/(Ksoilwater) = **4.43E+02 µg/L**

Emission to STP/separate sewer system (urban area):

Emission rate to STP/separate sewer sysems is used to calculate the PEC in the relevant compartments based on the dicument [Assessment of direct emission to surface water in urban areas (UBA, 2014)](https://echa.europa.eu/documents/10162/16908203/pt_6_7_8_9_10_assessment_of_direct_emission_surface_water_urban_areas_en.pdf/56073606-24c6-4b77-89ea-bfeec98d5943).

Calculation after degradation of active chlorine in the sewer system:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 4.89E-19 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

**Bridge over pond scenario (direct releases to water)**

Calculations were done considering two guidance documents. Characteristics of the bridge are from ESD PT8 and models and parameters governing spray application (losses of product, etc.) are from ESD PT10.

For this scenario, in order to not to be in a too worst case situation, only application is considered.

**Emission scenario for calculating the releases from a bridge treated by sprayer (ESD PT10 and ESD PT8)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Unit** | **Value** | **Source** | **Guidance document** |
| Treated area per day | AREA | m².d-1 | 10 | D | ESD PT8 |
| Volume of product applied on area | V form | l.m-2 | 0.1 | S |  |
| Concentration ofsubstance  Active chlorine  Chlorate | C form | g.l-1 | 67.8  0.59 | S | For active chlorine, based on the density of the product of 1.13 |
| Fraction of product lost during application by spray drift | F drift | - | 0.1 | D | ESD PT10 |
| Fraction of product lost during application due to runoff | F runoff | - | 0.2 | D | ESD PT10 |
| Water volume under bridge | V water | m3 | 1000 | D | ESD PT8 |

Fraction of product lost during brush application initially described in ESD PT8 is replaced by fractions of product lost due to spray drift and runoff described in ESD PT10 (spray application on House).

Local emission of active substance during application due to spray drift

*Elocal drift = AREA x V form x C form x F drift x E-3*

Local emission of active substance during application due to runoff

*Elocal runoff = AREA x V form x C form x F runoff x E-3*

Emission to local water during day of emission

*Elocal water = Elocal drift + Elocal runoff*

Local concentration in water (pond) during day of emission

*Clocal water = Elocal water / V water*

**Emissions and concentrations local water and concentration in water during application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Usage scenario** | **Symbol** | **Receiving Compartment** | **Output** | |
|  |  |  | Active chlorine | Chlorate |
| PT10: Spray application PT8: Pond under bridge | Elocal water | Pond under bridge | **Emission rate to water (kg.d-1):** | |
| 2.03E-02 | 1.77E-03 |
| Clocal water | Pond under bridge | **Concentration in water (mg.l-1):** | |
| 2.03E-02 | 1.77E-03 |

**PT4 scenarios**

##### PT4 - Scenario 1: Disinfection of entire plants IHO (2006) (Meta-SPC 1, 2, 3 7) covering use 5 - Disinfection of hard surfaces in contact with food: (e.g. breweries, dairies, beverage processing plants) , use 6 – Disinfection of equipment/materials by automatic spraying in closed systems (tunnels), use 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (CIP) and use 9– Disinfection of inner surfaces in veterinary water systems

Local emission due to disinfection of equipment/materials by automatic spraying in closed systems (tunnels) and by cleaning in place (CIP), the disinfection of inner surfaces in contact with food (e.g. breweries, dairies, beverage processing plants) and in veterinary water systems were calculated using the ESD for PT4 Disinfection of entire plants (SCC, 2011).

In food, drink and milk industries (FDM), multiple disinfection processes may take place at the same time in several different units (e.g. CIP, disinfection of storage tanks, disinfection of surface, disinfection of process lines…) using the same disinfectant.

FDM are considered as a local point source of emission. This ESD is providing a method to assess the emission from the entire plant.

The emission estimation is based on the consumption of disinfectant by a model plant. As no annual tonnage for a local plant was known for the products assessed, the default data for chlorine given in the ESD was used (228 kg/yr).

The SoC is present in the meta-SPC 1 and thus is assessed quantitatively below. The default data for chlorine is adapted to the SoC by comparing the percentage of active chlorine in meta-SPC 1 of 5% and the percentage of SoC of 8% to estimate an annual tonnage: QaiSoC=8 %\*228kg/yr /5%= 364.8 kg/y

We can also estimate the chlorate emission based on the active chlorine, where a worst-case concentration of 3.2% w/w chlorate was defined for the Meta-SPC 2, corresponding to a nominal concentration of 12.5% w/w active chlorine, it can be deducted that a worst-case of 0.256 kg chlorate/kg active chlorine is relevant to be considered.

Depending of plant, after disinfection, wastewater may be released to a public sewer system (off-site STP) or to an on-site STP. After an on-site STP, wastewater is assumed to be directly released to surface water.

Input parameters for the emission scenario - Disinfection of hard surfaces, in contact with food: Assessment of entire plants:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Amount of biocidal active substance used per year in the local plant:  Active chlorine  Chlorate  SoC | kg/y | Qai | D | 228  58.37  364.8 | Default value for annual consumption of chlorine per plant according to ESD |
| Number of emission days per year | d/y | Temission | D | 231 |  |
| Fraction released to wastewater | [-] | Fwater | D | 1 | 100% of solution released to wastewater assumed for tier 1 |

Output:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | **Active chlorine** | **SoC** | **Chlorate** |
| Emission rate to wastewater (standard STP) – before degradation | kg/d | Elocalwastewater | **9.87E-01** | **1.58** | **2.53E-01** |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | **Elocalwastewater = 4.39E-20kg/d** |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT4 - Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries (Meta-SPC 1, 2, 3, 7) covering use 5 - Disinfection of hard surfaces in contact with food (e.g. floors, walls, furniture, equipment, drains, sinks…)

This scenario covers the use “Disinfection of hard surfaces in contact with food”. The local emission is based on the application rate of disinfectant per m2 and the area of the treated surface. The main fraction of residues is released to the sewer system.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below with the worst case product of each META-SPC:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Meta-SPC 1 | | | Meta-SPC 2 | | Meta-SPC 3 | Meta-SPC 4 | Meta-SPC 6 | | Meta-SPC 7  (gel | | |
| Substances | Active chlorine | | Chlorate | Active chlorine | Chlorate | Active chlorine | Active chlorine | Active chlorine | Chlorate | Active chlorine | chlorate | |
| Concentration of substance | 6.3 (%w/w) | | 0.73 (%w/v) | 12.5 (%w/w) | 3.2 (%w/v) | 2.6 (%w/w) | 2.6 (%w/w) | 4.8 (%w/w) | 0.82 (W/v) | 2.2 (%w/w) | 0.15 (%w/v) | |
| Dilution factor (-) | 0.06 | 0.066 | | 0.040 | | 0.177 | 0.08 | 0.044 | | 0.7 | | |
| Density | 1.1341 | 1.1451 | | 1.2106 | | 1.0521 | 1.03 | 1.075 | | 1.15 | | |
| Concentration in working solution g/L | 4.287 | | 0.48 | 6.053 | 1.28 | 4.84 | 2.14 | 2.27 | 0.36 | 1.77 | | 0.11 |
| Application rate of active substance (g/m2) considering 0.1 L/m2 | 0.4287 | | 0.048 | **0.6053** | **0.128** | 0.484 | 0.214 | 0.227 | 0.036 | 0.177 | | 0.011 |

The Meta-SPC 3 is considered as the worst-case and will be used for the calculations for the active substance and Meta-SPC 2 the worst-case for chlorates.

**Dose for the SoC:**

The substance of concern is only present in Meta-SPC 1 at 8% and thus its dose can be estimated : 8 %\*0.066\*1.1451 g/L \* 0.1 L/m2= 0.604 g/m2 (considering the worst dilution and density of the Meta-SPC 1 products)

An application rate of 0.1 L/m² (based on Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019, in case of absence of more specific information.

***Elocal calculation for Scenario 2***

The local release to wastewater was calculated according to the following equation:

|  |
| --- |
| Elocalwater = Qa.i.appl • AREAsurface • Nappl • (1 - Fdis) • (1 – Felim) • Fwater / 1000 |

By default, one application per day is considered as a reasonable worst-case value.

Input parameters for the emission scenario - Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Input** | **Nomenclature** | | **Value** | | | **Unit** | | **Remarks** |
|  | **Active chlorine** | | **Chlorate** | **SoC** | |  |
| Application rate of the active substance | Qa.i.appl | 6.05E-01 | | 1.28E-01 | 6.04E-01 | | g/m2 | See above |
| Surface area to be disinfected for slaughterhouses | AREAsurface | 10 000 | | | | | m2 | Default |
| Surface area to be disinfected for kitchens & canteens | AREAsurface | 2 000 | | | | | m2 | Default |
| Number of applications per day | Nappl | 1 | | | | | d-1 |  |
| Fraction of substance disintegrated during or after application, before release to the sewer system | Fdis | 0 | | | | | - | Default |
| Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water | Felim | 0 | | | | | - | Default |
| Fraction released to wastewater | Fwater | 1 | | | | | - | Default |

Output:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Qa.i.appl\*AREAsurface\*Nappl\*(1-Fdis)\*(1-Felim)\*Fwater/1000 | | | | | |
|  | | | Slaughterhouses | Catering kitchens |  |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 6.05E+00 | 1.21E+00 | As Active chlorine eq Cl2 |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 1.28E+00 | 2.56E-01 | As Chlorate |
| Emission rate to wastewater (standard STP) | kg/d | Elocalwater | 6.04E+00 | 1.21E+00 | As SoC |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Slaughterhouse:  Elocalwater = 2.69E-19 kg av Cl/d    Catering kitchens:  Elocalwater = 5.38E-20 kg av Cl/d |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT4 - Scenario 3: Disinfection of milking parlour systems (Meta-SPC 1, 2, 3) covering the use 8 – Disinfection of hard surfaces in food and feed areas by cleaning-in-place (e.g. milk and dairy production (CIP))

Local emission due to disinfection of milking parlour systems were calculated using the ESD for PT4 Disinfection of milking parlour systems (SCC, 2011).

This scenario covers the disinfection of hard surfaces (e.g pipelines, tubes, separative membranes/ion exchangers and tanks of filling machines or similar)”. Disinfection is performed by CIP. Wastewater is then discarded to sewer system.

The products are used by pouring in food and feed areas (e.g. beverage production, milk and dairy production, green house watering, etc.) by circulation (CIP).

Concerning green house watering, according to the TAB ENV v.2.0, ENV-A9, the disinfection in greenhouses is performed indoor and the emissions to the STP can be considered as negligeable, and thus covered by the current assessment.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Meta-SPC 1 | | | Meta-SPC 2 | | Meta-SPC 3 |
| Substances | Active chlorine | Chlorate | SoC | Active chlorine | Chlorate | Active chlorine |
| Concentration of active substance | 6.3  (% w/w) | 0.73  (% w/v) | 8  (% w/w) | 12.5  (% w/w) | 3.2  (% w/v) | 2.6  (% w/w) |
| Dilution factor | 0.06 | 0.066 | | 0.040 | | 0.177 |
| Density | 1.1341 | 1.1451 | | 1.2106 | | 1.0521 |
| Concentration in working solution (g/L) | 4.29 | 0.48 | **6.04** | **6.05** | **1.28** | 4.84 |

The Meta-SPC 2 is considered as the worst-case and will be used for the calculations for the active substanceand for the chlorates.

The SoC is only present in the Meta-SPC 1 and its corresponding dose has also been calculated.

Input parameters for the emission scenario - Disinfection of milking parlour systems:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable/parameter** | **Unit** | **Symbol** | **S/D/O/P** | **Value** | **Remark** |
| Concentration of:  Active chlorine  Chlorate  SoC | g/L | Cform | S | 6.05E+00  1.28E+00  6.04E+00 |  |
| Amount of disinfectant used for cleaning of the milking installation | L/d | Vforminst | D | 130 | Based on ESD: 65L per application is used for cleaning of the milking installation. As milking installation are usually cleaned twice a day, an amount of 130L per day (65 x 2) was considered for the assessment. |
| Amount of disinfectant used for cleaning of the milk storage tank | L/d | Vformtank | D | 45 |  |
| Fraction of substance disintegrated during or after application (before release to the sewage system) | [-] | Fdis | D | 0 |  |
| Fraction of the emission to wastewater | [-] | Fwater | D | 1 |  |

Output:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Quantity of active ingredient used | g/d | Qai | 1.06E+03 | As Active chlorine eq Cl2 | Qai = Cform \* (Vforminst + Vformtank) |
| 2.24E+02 | As Chlorate |
| 1.06E+03 | As SoC |
| Local emission to wastewater | kg/d | Elocalwater | 1.06E+00 | As Active chlorine eq Cl2 | Elocalwater = Qai \* (1-Fdis) \* Fwater /1000 |
| 2.24E-01 | As Chlorate |
| 1.06E+00 | As SoC |

Calculation after degradation of active chlorine in sewer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | **Elocal,water= 4.71E-20 kg/d** |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

##### PT4 - Scenario 4: Disinfection of equipment/materials by immersion (Meta-SPC 2 & 3) covering use 7 – Disinfection of equipment/materials by immersion/soaking

In the ESD for PT4, no scenario regarding immersion is included.

Therefore, the reasoning used for a substance seen at WGV209 (glyoxal) is applied in the frame of this dossier.

The disinfection of equipment by dipping is mentioned in the section 2.2 of the ESD (Disinfection in large scale kitchens, canteens, slaughterhouses and butcheries) as followed (ESD-TP04 (2011) – tables 7 and 8):

* In slaughterhouses and butcheries, dipping could be applied for cutting boards, depending on size (once per week).
* In large scale catering kitchens and canteens, dipping could be applied for cutting boards and food containers, depending on size (1 – 2 times per day); after contact with critical foods (meat, poultry, fish, eggs); for slicers (1 – 2 times per day and if required).

The scenario proposes to consider that the equipment is disinfected in dipping baths with a capacity of up to 100 liters and that the bath content will be disposed of to drain once per day. This volume of solution is considered not to fit with large scale facilities, but rather to small or medium areas.

According to the ESD for PT04, wastewaters from catering kitchens and canteens are diluted with the wastewater streams from other premises. It can be expected as a realistic typical case scenario that several small to medium scale facilities using baths containing glyoxal as disinfecting solution are connected to the same sewage treatment plant. The scenario therefore proposes to consider that 5 sites at the STP scale use 100 liters on a daily basis.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Meta-SPC 2 | | Meta-SPC 3 |
| Substances | Active chlorine | Chlorate | Active chlorine |
| Concentration of substance | 12.5 (% w/w) | 3.2 (% w/v) | 2.6 (% w/w) |
| Dilution factor | 0.040 | | 0.177 |
| Density | 1.2106 | | 1.0521 |
| Concentration in working solution (g/L) | **6.053** | **1.28** | 4.84 |

The Meta-SPC 2 is considered as the worst-case and will be used for the calculations for the active substance.

There is no assessment of chlorate needed for meta-SPC 3 and thus the dose of chlorates in meta-SPC 2 will be used.

No SoC is present in these Meta-SPC.

Input parameters for the emission scenario - Disinfection of equipment/materials by immersion:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/parameter** | **Symbol** | **Unit** | **Value** | **Source** |
| Concentration of:  Active chlorine  Chlorate | Cform | [g/L] | 6.053E+00  1.28E+00 | S |
| Volume of one dipping bath | Vbath | [L] | 100 | D |
| Number of sites connected to the same STP using the disinfection solution | Nappl | [-] | 5 | D |
| Fraction of substance disintegrated during or after application (before release to the sewer system) | Fdis | - | 0 | D (ESD) |
| Fraction of substance eliminated due to onsite pre-treatment of waste water | Felim | - | 0 | D (ESD) |
| Fraction released to waste water | Fwater | - | 1 | D (ESD) |

Output:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Local emission to wastewater | kg/d | Elocalwater | 3.03E+00 | As Active chlorine eq Cl2 | Elocalwater = Cformx Vbath x Nappl x (1 – Fdis) x (1 – Felim) x Fwater |
| 6.40E-01 | As Chlorate |

Calculation after degradation of active chlorine in swer before the STP:

|  |  |
| --- | --- |
| Calculation:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | **Elocal,water= 1.345E-19 kg/d** |

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway – Av Cl** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Representative scenario** | **STP** | **Freshwater incl. sediment** | **Marine** | **Soil incl. groundwater** | **Air** |
| **PT2** | | | | | |
| Scenario 1a & 1b: Disinfection in institutional areas Lavatory/General purpose | Q | Q | Q | Q | Q |
| Scenario 2: Disinfection in industrial premises (non-medical sector) | Q | Q | Q | Q | Q |
| Scenario 3: Disinfection of rooms, furniture and objects (medical sector) | Q | Q | Q | Q | Q |
| Scenario 4: Disinfection of equipment and instruments by immersion | Q | Q | Q | Q | Q |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces | Q | + | Q | Q | Q |
| **PT4** | | | | | |
| Scenario 1: Disinfection of hard surfaces, in contact with food - Assessment of entire plants | Q | Q | Q | Q | Q |
| Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries | Q | Q | Q | Q | Q |
| Scenario 3: Disinfection of milking parlour systems | Q | Q | Q | Q | Q |
| Scenario 4: Disinfection of equipment and instruments by immersion | Q | Q | Q | Q | Q |

Q: Qualitative assessment considering negligible emissions

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure pathway – Chlorate** | | | | | | |
| **Representative scenario** | **STP** | **Freshwater** | **Marine** | **Soil** | **Groundwater** | **Air** |
| **PT2** | | | | | | |
| Scenario 1a & 1b: Disinfection in institutional areas – Lavatory/General purpose | a | SQ | a | a | SQ | a |
| Scenario 2: Disinfection in industrial premises (non-medical sector) | A | SQ | a | a | SQ | a |
| Scenario 3: Disinfection of rooms, furniture and objects (medical sector) | A | SQ | a | a | SQ | a |
| Scenario 4: Disinfection of equipment and instruments by immersion | A | SQ | a | a | SQ | a |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces | A | SQ | a | a | SQ | a |
| **PT4** | | | | | | |
| Scenario 1: Disinfection of hard surfaces, in contact with food – Assessment of entire plant | A | SQ | a | a | SQ | a |
| Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries | A | SQ | a | a | SQ | a |
| Scenario 3: Disinfection of milking parlour systems | A | SQ | a | a | SQ | a |
| Scenario 4: Disinfection of equipment and instruments by immersion | A | SQ | a | a | SQ | a |

SQ: Semi Qualitative assessment; a: covered by the active substance assessment

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure pathway – SoC** | | | | | | |
| **Representative scenario** | **STP** | **Freshwater** | **Marine** | **Soil** | **Groundwater** | **Air** |
| **PT4** | | | | | | |
| Scenario 1: Disinfection of hard surfaces, in contact with food – assessment of entire plant | ++ | + | n.r. | + | + | n.r. |
| Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries | ++ | + | n.r. | + | + | n.r. |

n.r.: not relevant

Input parameters for calculating the fate and distribution of chlorate in the environment are summarised below using different tools and sources:

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment – chlorate** | | | |
| *Input* | *Value* | *Unit* | *Remarks* |
| Molecular weight | 83.5 | g/mol | - |
| Vapour pressure (at 25°C) | 3.50E-07 | Pa | - |
| Water solubility (at 25°C) | 7.36E+05 | mg/L | at pH 4.49 to 8.70 |
| Organic carbon/water partition coefficient (Koc) | 31.62 | L/kg | QSAR (KOCWIN v2.00) |
| Henry’s Law Constant  (at 20 oC) | 5.2E-09 | Pa/m3/mol | Estimated |
| Biodegradability | Not applicable to inorganic substances | [-] | Not readily biodegradable |
| DT50 for degradation in soil | 1E+06 | d (at 12ºC) | Not Readily biodegradable |
| Rate constant for soil biodegradation | 6.93E-07 | d-1 (at 12ºC) |  |

The inputs for Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS n° 308062-28-4) come from the REACH registration dossier of the substance:

<https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/15191>

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment – SoC** | | | |
| *Input* | *Value* | *Unit* | *Remarks* |
| Molecular weight | 243 | g/mol | - |
| Vapour pressure (at 20°C) | 7.50E-05 | Pa | - |
| Water solubility (at 20°C) | 409.5 | g/L | - |
| Organic carbon/water partition coefficient (Koc) | 1746.4 | L/kg | In order to calculate the Koc value for use in the exposure assessment, Kom values were converted into Koc values using the relationship soil organic matter = 1.724 x soil organic carbon content. The Kom value for the C12 homologue in soil 543151 was excluded from calculations as a suspected outlier due to the low percentage organic carbon of the soil type used, which may limit correlation with organic carbon content, and since the data failed to correlate with the increased affinity for soils anticipated to be demonstrated by the C14homologue. The Koc values were then used to calculate the theoretical distribution coefficient Kd normalised to 2% organic carbon. The geometric mean of the Kd values was calculated as 46.8 L/kg, equivalent to a Koc of 1525 L/kg |
| Log Kow | 2.7 | - | - |
| Biodegradability | Readily biodegradable | [-] | Meeting the 10-day window |
| DT50 for degradation in soil | 30 | d (at 12ºC) | Default value |

The distribution of chlorate and SoC within STP has been estimated using the SimpleTreat 4.0 Model:

**Chlorate**

|  |  |  |
| --- | --- | --- |
| **Compartment** | **Percentage [%]** | **Remarks** |
| Air | 1E-08 | - |
| Water | 99.6 | - |
| Sludge | 0.394 | - |
| Degraded in STP | 0 | - |

**Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides**

|  |  |  |
| --- | --- | --- |
| **Compartment** | **Percentage [%]** | **Remarks** |
| Air | 9.17E-09 | - |
| Water | 7.09 | - |
| Sludge | 13.26 | - |
| Degraded in STP | 79.65 | - |

***Calculated PEC values***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Active chlorine** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| Scenario 1a & 1b: Disinfection in institutional areas – Lavatory/General purpose | Q | Q | Q | Q | Q |
| Scenario 2: Disinfection in industrial premises (non-medical sector) | Q | Q | Q | Q | Q |
| Scenario 3: Disinfection of rooms, furniture and objects (medical sector) | Q | Q | Q | Q | Q |
| Scenario 4: Disinfection of equipment and instruments by immersion | Q | Q | Q | Q | Q |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  House releases | Q | Q | Q | Q | Q |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond (application only) | Q | 2.03E-02 | Q | Q | Q |
| **PT4** | | | | | |
| Scenario 1: Disinfection of hard surfaces, in contact with food – Entire plant | Q | Q | Q | Q | Q |
| Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses | Q | Q | Q | Q | Q |
| Scenario 3: Disinfection of milking parlour systems | Q | Q | Q | Q | Q |
| Scenario 4: Disinfection of equipment and instruments by immersion | Q | Q | Q | Q | Q |

Q: Qualitative assessment considering negligible emissions

Concerning the scenario 5: anti-algae treatment of hard surfaces, the direct release to surface water has been assessed via the bridge over the pond scenario. The PEC takes into account the application phase only.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Chlorate** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| Scenario 1a & 1b: Disinfection in institutional areas –  - Lavatory  - General | a | 7.47E-04  1.59E-03 | a | 1.63E+00  3.47E+00 | n.r. |
| Scenario 2: Disinfection in industrial premises (non-medical sector) | a | 6.37E-03 | a | 1.39E+01 | n.r. |
| Scenario 3: Disinfection of rooms, furniture and objects (medical sector) | a | 2.88E-03 | a | 6.26E+00 | n.r. |
| Scenario 4: Disinfection of equipment and instruments by immersion | a | 1.91E-02 | a | 4.16E+01 | n.r. |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  House - Urban STP  House – Urban separate sewer system  Total release considering application and service-life | a  n.r. | 4.76E-02  1.59E-01 | a  n.r. | 1.04E+02  n.r. | n.r. |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  House - Rural direct release to soil  Total release considering application and service-life | n.r. | n.r. | a | 4.43E+02 | n.r. |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | a | 1.77E-03 | a | a | n.r. |
| **PT4** | | | | | |
| Scenario 1: Disinfection of entire plant | a | 1.26E-02 | a | 2.74E+01 | a |
| Scenario 2: Disinfection in :  - large scale catering kitchens, canteens  - slaughterhouses | a | 1.27E-02  6.37E-02 | a | 2.78E+01  1.39E+02 | a |
| Scenario 3: Disinfection of milking parlour systems | a | 1.12E-02 | a | 2.43E+01 | a |
| Scenario 4: Disinfection of equipment and instruments by immersion | a | 3.19E-02 | a | 6.94E+01 | a |

a: covered by the active substance assessment

n.r.: not relevant

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – SoC** | | | | | |
|  | **PECSTP** | **PECwater covering sediment as EPM** | **PECsoil\*** | **PECGW\*\*** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| PT04 - Scenario 1: Disinfection of entire plant | 5.60E-02 | 5.58E-03 | 2.81E-01 | **2.97** | n.r. |
| PT04 - Scenario 2: Disinfection in :  - large scale catering kitchens, canteens  - slaughterhouses | 4.29E-02  2.14E-01 | 4.28E-03  2.14E-02 | 2.15E-01  1.08 | **2.29**  **11.4** | n.r. |
| PT04 – Scenario 3: Disinfection in milking parlour systems | 3.75E-02 | 3.75E-03 | 1.88E-01 | **2.00** | n.r. |

\*twa over 30 days

\*\* Based on PECsoil twa over 180 days

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not likely to occur as the products of the Oxena family are intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for active chlorine as it does not bioaccumulate nor bioconcentrate due to its high water solubility and rapid degradation in the environment.

No secondary poisoning is expected for chlorate as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

No secondary poisoning is expected for SoC as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

#### Risk characterisation

A qualitative risk characterization of chlorate is presented for all the environmental compartments as covered by the active substance, except for groundwater as chlorate is a substance of concern in relation to human health. Therefore, a semi-qualitative risk assessment is proposed for groundwater and surface water intented for the abstraction of drinking water, with a comparsion with the WHO value of 700 µg/L.

A quantitative assessment is presented for the substance of concern for all the environmental compartments

The PECs calculated for the air compartment are considered negligible.

Active chlorine

Risk characterisation of the active substance is summarized in the following table for each environmental compartment. Results are presented for the three emission scenarios, with degradation of the active substance in the sewer system as it represents the most realistic case in view of the active substance properties.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values – Active chlorine** | | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PEC/LimitGW** | **PECair** |
| Scenario 1a & 1b: Disinfection in institutional areas – Lavatory/General purpose | negligible | negligible | negligible | negligible | negligible |
| Scenario 2: Disinfection in industrial premises (non-medical sector) | negligible | negligible | negligible | negligible | negligible |
| Scenario 3: Disinfection of rooms, furniture and objects (medical sector) | negligible | negligible | negligible | negligible | negligible |
| Scenario 4: Disinfection of equipment and instruments by immersion | negligible | negligible | negligible | negligible | negligible |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  House releases | negligible | negligible | negligible | negligible | negligible |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | negligible | 4.84E+02 | negligible | negligible | negligible |
| **PT4** | | | | | |
| Scenario 1: Disinfection of hard surfaces, in contact with food – Entire plant | negligible | negligible | negligible | negligible | negligible |
| Scenario 2: Disinfection in large scale catering kitchens, canteens, slaughterhouses | negligible | negligible | negligible | negligible | negligible |
| Scenario 3: Disinfection of milking parlour systems | negligible | negligible | negligible | negligible | negligible |
| Scenario 4: Disinfection of equipment and instruments by immersion | negligible | negligible | negligible | negligible | negligible |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values – Chlorate** | | | | | |
|  | **PEC/PNECSTP** | **PECsurface water intented for the abstraction of drinking water /LimitGW\*** | **PEC/PNECsoil** | **PECGW//LimitGW\*** | **PECair** |
| Scenario 1a & 1b: Disinfection in institutional areas –  - Lavatory  - General purpose | a | 1.07E-03  2.28E-03 | a | 2.32E-03  4.96E-03 | n.r. |
| Scenario 2: Disinfection in industrial premises (non-medical sector) | a | 9.11E-03 | a | 1.98E-02 | n.r. |
| Scenario 3: Disinfection of rooms, furniture and objects (medical sector) | a | 4.11E-03 | a | 8.95E-03 | n.r. |
| Scenario 4: Disinfection of equipment and instruments by immersion | a | 2.73E-02 | a | 5.95E-02 | n.r. |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  House - Urban STP  House – Urban separate sewer system  Total release considering application and service-life | a | 6.80E-02  2.28E-01 | a | 1.48E-01  n.r. | n.r. |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  House - Rural direct release to soil  Total release considering application and service-life | n.r. | n.r. | n.r. | 6.33E-01 | n.r. |
| Scenario 5: Anti-lichen and anti-algae treatment of hard surfaces  Bridge over the pond | n.r. | 2.53E-03 | n.r. | n.r. | n.r. |
| **PT4** | | | | | |
| Scenario 1: Disinfection of hard surfaces, in contact with food – Entire plant | a | 1.80E-02 | a | 3.92E-02 | a |
| Scenario 2: Disinfection in :  - large scale catering kitchens, canteens  - slaughterhouses | a | 1.82E-02  9.11E-02 | a | 3.97E-02  1.98E-01 | a |
| Scenario 3: Disinfection of milking parlour systems | a | 1.59E-02 | a | 3.47E-02 | a |
| Scenario 4: Disinfection of equipment and instruments by immersion | a | 4.55E-02 | a | 9.91E-02 | a |

a: covered by the active substance assessment

\* compared to the drinking water limit value of 700 µg chlorate/L (WHO drinking water limit) for water disinfected by chloration.

n.r.: not relevant

Conclusions: Risks are considered unacceptable for the scenario PT02-5: Anti-lichen and anti-algae treatment of hard surfaces for the aquatic compartment for the active substance considering the direct releases to water (bridge over pond scenario).

Risks are considered acceptable for the active substance and for chlorate generated during storage for all other scenarios, considering a qualitative assessment with negligible emissions for every compartments, as well as semi qualitative assessment for chlorate in groundwater and freshwater intended for the abstraction of drinking water.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values – SoC** | | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater covering sediment as EPM** | **PEC/PNECsoil twa** | **PECGW**  **[µg/L]** | **PECair** |
| Scenario 1: Disinfection of hard surfaces, in contact with food – Entire plant | 2.33E-03 | 1.64E-01 | 2.68E-01 | **2.98** | n.r. |
| PT04 - Scenario 2: Disinfection in :  - large scale catering kitchens, canteens  - slaughterhouses | 1.79E-03  8.92E-03 | 1.26E-01  6.28E-01 | 2.05E-01  **1.02** | **2.29**  **1.14E+01** | n.r. |
| PT04 – Scenario 3: Disinfection in milking parlour systems | 1.56E-03 | 1.10E-01 | 1.79E-01 | **2.00** | n.r. |

Conclusions:

Unacceptable risks are foreseen for the groundwater for all the scenarios, and for the soil for slaughterhouse.

Nevertheless, for the terrestrial compartment, the RCR value is only slightly over the trigger of 1, and considering the worst case situation of the slaughterhouse scenario, this can be considered acceptable (see more details on this justification in the confidential PAR).

***Refinement for groundwater***

The groundwater compartment presents PEC values > 0.1 µg/L for the SoC. This value indicates a potential risk to groundwater. A more realistic, higher-tier assessment of the potential for groundwater contamination associated with the sludge applications of the SoC has also been carried out using the simulation model FOCUS-PEARL 4.4.4.

The leaching potential of SoC was investigated by simulating applications to two standard crops (Maize and alfalfa). Simulations was performed for all nine FOCUS scenarios.

According to the TAB, an effective application rate per hectare with sludge contribution is given by:

Application rate for agricultural land (kg/ha) = 5000 x [Cdry sludge] x 10-6

Application rate for grassland (kg/ha) = 1000 x [Cdry sludge] x 10-6

The worst-case total concentration of SoC in combined sludge of Scenario 1 + Scenario 2 + Scenario 3= 1660 mg/kg

The FOCUS-Pearl model considers 26 year of simulation, for the maize crops with one application per year, 20 days before crop emergence, and for the alfalfa crops with one application per year on the 1st of March are simulated.

| **Relevant input variables in FOCUS PEARL 4.4.4** | |
| --- | --- |
| **Parameter** | **Value** |
| Scenario | |
| Location | All 9 EU scenario |
| Years of simulation | 26 |
| Standard crop | Maize and alfalfa |
| Application rate of STP sludge (kg/ha) | **Agricultural land (Maize):** |
| 5000 x Cdry sludge x 10-6 = 8.3 kg/ha/y |
| **Grassland (Alfalfa):** |
| 1000 x Cdry sludge x 10-6 = 1.66 kg/ha/y |
| Application depth | Incorporation 20 cm (maize) |
| Incorporation 10 cm (alfalfa) |
| Date of application | **Maize:** One application per year, 20 days before crop emergence |
| **Grassland (alfalfa):** One application per year on the 1st of March |
| **SoC** | |
| Deposition | No deposition |
| Molar mass (g.mol-1) | 243 |
| Vapour pressure (Pa at 20°C) | 7.5E-05 |
| Water solubility (g.L-1 at 20°C) | 409.5 |
| Kom (L.kg-1 at 20°C) | 1013 |
| Freundlich exponent | 1 |
| DT50 soil (d at 12°C) | 30 |
| Coefficient for uptake for plant | 0 |
| Molar activation energy (kJ.mol-1) | 65.4 |

Results are presented in the following tables for both grassland and arable land.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Overview of result for maize crop from FOCUS PEARL** | | |
| **Result-text** | **Grassland** | **Arable land** | **Location** |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | CHATEAUDUN |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | HAMBURG |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | - | JOIKONEN |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | KREMSMUENSTER |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | OKEHAMPTON |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | PIACENZA |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | PORTO |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | SEVILLA |
| Concentration closest to the 80th percentile(µg/L) | 0.00000 | 0.00000 | THIVA |

For all locations, the values are below the threshold value of 0.1 µg/L for both grassland and arable land. Therefore no unacceptable risks are foreseen for the SoC after FOCUS refinement.

***Primary and secondary poisoning***

Primary poisoning is not likely to occur as the products are intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for active chlorine as it does not bioaccumulate nor bioconcentrate due to its high water solubility and rapid degradation in the environment.

No secondary poisoning is expected for chlorate as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

No secondary poisoning is expected for SoC as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

***Mixture toxicity***

A quantitative assessment has been performed only on the SoC and thus a mixture toxicity assessment is not relevant in the case of this dossier.

***Aggregated exposure (combined for relevant emmission sources)***

According to the WG-I-2020 Part B, a qualitative assessment for the active substance has been performed due to its high reactivity with organic matter. Consequently, the aggregated exposure is relevant for chlorates and the substance of concern separately.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

The aggregate risks assessment presented below sums up the SoC risk ratios from all uses and the chlorates assessment for groundwater and surface water intendeed for drinking water, in case of release to STP.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values - Chlorates** | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater intented for the abstraction of drinking water\*** | **PEC/PNECsoil** | **PECGW/PNEC GW\*** |
|  | negligible | 3.01E-01 | negligible | 6.55E-01 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values - SoC** | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PECGW** |
|  | 1.46E-02 | 1.03 | 1.68 | <0.1 after refinement |

Conclusion: Aggregated risks for chlorate are acceptable for all compartments. Risks are foreseen for SoC. Nevertheless, an aggregated risks considering all the scenarios seems too be too worst case.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product family** |
| Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance NaOCl leading to negligible emissions to the environment, considering a semi-qualitative assessment of chlorate for groundwater and surface water intended for the abstraction of drinking water and a quantitative assessment of the substance of concern : Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS n° 308062-28-4), for the following uses:   * PT2 disinfection of sanitary installations (e.g toilet bowls, drains, sink): Meta SPC 2, 3, 4, 6, 7 * PT2 disinfection of hard surfaces (non-medical sector): Meta SPC 2, 3, 4, 6, 7 * PT2 disinfection of hard surfaces (medical-sector): Meta SPC 2, 3 * PT2 disinfection of equipment/materials by immersion/soaking: Meta-SPC 2, 3 * PT4 disinfection of hard surfaces in contact with food: Meta-SPC 1, 2, 3, 4, 6, 7 * PT4 disinfection of equipment/materials by automatic spraying in closed systems (tunnels): Meta-SPC 1, 2, 3 * PT4 disinfection of equipment/materials by immersion/soaking: Meta-SPC 2, 3 * PT4 disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion exchangers and tanks of filling machines or similar): Meta-SPC 1, 2, 3 * PT4 disinfection of inner surfaces in veterinary water systems: Meta-SPC 1, 2   Unacceptable risks are foreseen for direct releases into the aquatic compartment considering a quantitative assessment of NaOCl for:   * PT2 Anti-lichen and anti-algae treatment of hard surfaces: Meta-SPC 5   The following risk mitigation measure should be applied to limit the direct emissions of product to the aquatic compartment:  ***Do not apply where the product can reach surface water*** |

### Measures to protect man, animals and the environment

*See the Summary of Products Characteristics § 2.1*

### Assessment of a combination of biocidal products

*Not relevant*

### Comparative assessment

*Not relevant*

# Annexes[[16]](#footnote-17)

## List of studies for the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section considered in PAR** | **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner** |
| 2.2.2 | Demangel, B. | 2019 | Surface tension and viscosity test on ALCA (= OXE ALCA)  Report N°R18-918046-001 | Yes | Oxena |
| 2.2.2 | Demangel, B. | 2019 | Surface tension and viscosity test on DECAP ACM (= OXE ALCA CHLORE MOUSSANT)  Report N°R18-918046-002 | Yes | Oxena |
| 2.2.2 | Demangel, B. | 2019 | Surface tension and viscosity test on JAVEL 12.5  Report N°R18-918046-003 | Yes | Oxena |
| 2.2.2 | Demangel, B. | 2019 | Surface tension and viscosity test on JAVEL 2.6 CITRON  Report N°R18-918046-004 | Yes | Oxena |
| 2.2.2 | Demangel, B. | 2019 | Surface tension and viscosity test on JAVEL 2.6 DETERGENT CITRON  Report N°R18-918046-005 | Yes | Oxena |
| 2.2.2 | Guy, B | 2018 | FINAL REPORT  Sodium hypochlorite  CAS number: 7681-52-9  EC number: 231-668-3  Analytical method validation of Sodium hypochlorite  Method  SANCO/3030/99 rev.4  Report No. RRCo-000304\_01 | Yes | Oxena |
| 2.2.2 | / | 2020 | Additional study on sodium chlorate determination | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | FINAL REPORT ALCA  CAS number: N/A  EC number: N/A  Density – pycnometer method  Report No. RRCo-000352\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | FINAL REPORT Deacp ACM  CAS number: N/A  EC number: N/A  Density – pycnometer method  Report No. RRCo-000353\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | FINAL REPORT JAVEL 12.5  CAS number: N/A  EC number: N/A  Density – pycnometer method  Report No. RRCo-000354\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | FINAL REPORT JAVEL 2.6 CITRON  CAS number: N/A  EC number: N/A  Density – pycnometer method  Report No. RRCo-000355\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | FINAL REPORT JAVEL DETERGENTE 2.6 CITRON  CAS number: N/A  EC number: N/A  Density – pycnometer method  Report No. RRCo-000356\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT ALCA (=OXE ALCA)  Stability storage test (accelerated)  Report No. RRCo-000324\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT Decap ACM (=OXE ALCA CHLORE MOUSSANT)  Stability storage test (accelerated)  Report No. RRCo-000325\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT JAVEL 12.5  Stability storage test (accelerated)  Report No. RRCo-000326\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT JAVEL 2.6  Stability storage test (accelerated)  Report No. RRCo-000327\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT JAVEL 2.6 CITRON  Stability storage test (accelerated)  Report No. RRCo-000328\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT JAVEL 2.6 DETERGENT CITRON  Stability storage test (accelerated)  Report No. RRCo-000329\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT JAVEL 4.8  Stability storage test (accelerated)  Report No. RRCo-000330\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2019 | GLP FINAL REPORT CLORIGEL (= GEL JAVEL PRO)  Stability storage test (accelerated)  Report No. RRCo-000389\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  ALCA  Reference: oxe alca  Batch: 18G002020  Stability storage tests (long-term)  Report No. RRCo-000380\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | GLP FINAL REPORT  Decap ACM (oxe alca chlore moussant)  Reference: N/A  Batch: 18G002910  Stability storage tests (long-term)  Report No. RRCo-000381\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Javel 12,5%  Reference: N/A  Batch: 18G002052  Stability storage tests (long-term)  Report No. RRCo-000382\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Javel 2.6%  Reference: N/A  Batch: 18M001902  Stability storage tests (long-term)  Report No. RRCo-000383\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Javel 2,6% parfum citron  Reference: N/A  Batch: 18G001902  Stability storage tests (long-term)  Report No. RRCo-000384\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Javel detergente citron 2.6 % chlore actif  Reference: N/A  Batch: 18G001990  Stability storage tests (long-term)  Report No. RRCo-000385\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Javel MIC 4.8% chlore actif (Berlingots)  Reference: N/A  Batch: 24247 24248  Stability storage tests (long-term)  Report No. RRCo-000386\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Gel javel pro oxena  Reference: 10781 CLORIGEL  Batch: LAD20181030  Stability storage tests (long-term)  Report No. RRCo-000390\_01 | Yes | Oxena |
| 2.2.2 | Peysson, W. | 2020 | REPORT (Not GLP document)  Mid-term REPORT (Not GLP document)  EXTIMUM  Stability storage tests (long-term)  Report No. RRCo-000614\_01 | Yes | Oxena |
| 2.2.2.7 | Demangel | 2021 | Surface tension and viscosity tests on CLORIGEL (GLP)  Report n° 18-918046-010 | Yes | Oxena |
| 2.2.3. | Zampieri, L | 2018 | Determination of the corrosivity to metals of sodium hypochlorite in sample Javel 4.8% Batch 24064 | Yes | Oxena |
| 2.2.3. | Zampieri, L | 2019 | Determination of the corrosivity to metals of sodium hypochlorite in sample Javel 2.6% Batch 18002195 | Yes | Oxena |
| 2.2.3. | Zampieri, L | 2019 | Determination of the corrosivity to metals of sodium hypochlorite in sample Javel 2.6% Batch 19M000218 | Yes | Oxena |

## Output tables from exposure assessment tools



## New information on the active substance

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)[[17]](#footnote-18)

## Confidential annex

See the confidential PAR

## Other

Environmental assessment of Disinfection-by-products by the applicant:

Meta-SPC 1 (FOOD INDUSTRY)

***Assessment of disinfection-by-products (DBPs)***

According to the European Union Risk Assessment (2007), during disinfection in industries and institutional areas about 1.275%[[18]](#footnote-19) of initial available chlorine will be converted in OBPs. Most of these by-products are produced during the release of the solution in the sewage system.

The proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation within European Union Risk Assessment (2007). About 9.1% (%OBPs) of chloroform and 2.9% (%OBPs) of trichloroacetic acid will be formed during disinfection.

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Disinfection of Agrifood industries |  |  |  |  |
| On-site STP | 6.35 x 10-5 | **1.32 x 10-3** | 2.02 x 10-5 | **2.02 x 10-7** |
| Off-site STP | 1.37 x 10-4 | **2.86 x 10-3** | 6.19 x 10-5 | **6.19 x 10-7** |
| Disinfection of milking parlour systems | 1.53 x 10-3 | **3.2 x 10-2** | 6.94 x 10-4 | **6.94 x 10-6** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-4 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Disinfection of Agrifood industries |  |  |  |  |
| On-site STP | 6.35 x 10-6 | **4.35 x 10-5** | 2.02 x 10-6 | **0.0119** |
| Off-site STP | 1.37 x 10-5 | **9.4 x 10-5** | 6.19 x 10-6 | **0.0364** |
| Disinfection of milking parlour systems | 1.53 x 10-4 | **1.05 x 10-3** | 6.94 x 10-5 | **4.08 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0.45 mg/kg dw** | | **PNECsed = 1.43 x 10-4 mg/kg dw** | |
| **PECsed (mg/kg dw)** | **PEC/PNECsed** | **PECsed (mg/kg dw)** | **PEC/PNECsed** |
| Disinfection of Agrifood industries |  |  |  |  |
| On-site STP | 5.22 x 10-6 | **4.35 x 10-5** | 1.7 x 10-6 | **0.0119** |
| Off-site STP | 1.13 x 10-5 | **9.4 x 10-5** | 5.21 x 10-6 | **0.0364** |
| Disinfection of milking parlour systems | 1.26 x 10-4 | **1.05 x 10-3** | 5.84 x 10-5 | **4.08 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0.56 mg/kg dw** | | **PNECsoil = 4.6 x 10-3 mg/kg dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Disinfection of Agrifood industries |  |  |  |  |
| On-site STP | 0 | **0** | 0 | **0** |
| Off-site STP | 2.94 x 10-7 | **1.27 x 10-5** | 2.12 x 10-7 | **7.51 x 10-3** |
| Disinfection of milking parlour systems | 3.28 x 10-6 | **1.42 x 10-4** | 2.37 x 10-6 | **8.41 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Groundwater***

Qualitative conclusion: As no groundwater reference value is available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to very low PECsoil values reflecting negligible emissions via STP sludge spreading and high degradation in presence of organic matter both in STP and in soil, exposure of groundwater is considered to be negligible.

Meta-SPC 2 (Bleach 9.6 - 12.5% professional)

***Assessment of disinfection-by-products (DBPs)***

According to the European Union Risk Assessment (2007), during disinfection in industries and institutional areas about 1.275%[[19]](#footnote-20) of initial available chlorine will be converted in OBPs. Most of these by-products are produced during the release of the solution in the sewage system.

The proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation. About 9.1% (%OBPs) of chloroform and 2.9% (%OBPs) of trichloroacetic acid will be formed during disinfection.

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 7.01 x 10-4 | **1.46 x 10-2** | 3.16 x 10-4 | **3.16 x 10-6** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 1.74 x 10-3 | **3.62 x 10-2** | 7.85 x 10-4 | **7.85 x 10-6** |
| Disinfection of milking parlour systems | 3.04 x 10-3 | **6.34 x 10-2** | 1.38 x 10-3 | **1.38 x 10-5** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-4 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 7.01 x 10-5 | **4.8 x 10-4** | 3.16 x 10-5 | **1.86 x 10-1** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 1.74 x 10-4 | **1.19 x 10-3** | 7.85 x 10-5 | **4.62** **x 10-1** |
| Disinfection of milking parlour systems | 3.04 x 10-4 | **2.08 x 10-3** | 1.38 x 10-4 | **8.09 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0,45 mg/kg dw** | | **PNECsed = 1,43 x 10-4 mg/kg dw** | |
| **PECsed (mg/kg dw)** | **PEC/PNECsed** | **PECsed (mg/kg dw)** | **PEC/PNECsed** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 5.76 x 10-5 | **4.8 x 10-4** | 2.66 x 10-5 | **1.86 x 10-1** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 1.43 x 10-4 | **1.19 x 10-3** | 6.61 x 10-5 | **4.62** **x 10-1** |
| Disinfection of milking parlour systems | 2.5 x 10-4 | **2.08 x 10-3** | 1.16 x 10-4 | **8.09 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0.56 mg/kg dw** | | **PNECsoil = 4.6 x 10-3 mg/kg dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 1.5 x 10-6 | **6.49 x 10-5** | 1.08 x 10-6 | **3.84 x 10-2** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 3.72 x 10-6 | **1.61 x 10-4** | 2.69 x 10-6 | **9.53 x 10-2** |
| Disinfection of milking parlour systems | 6.51 x 10-6 | **2.82 x 10-4** | 4.71 x 10-6 | **1.67 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Groundwater***

Qualitative conclusion: As no groundwater reference value is available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to very low PECsoil values reflecting negligible emissions via STP sludge spreading and high degradation in presence of organic matter both in STP and in soil, exposure of ground water is considered to be negligible exposure.

Meta-SPC 3 (Bleach 2.6% professional)

***Assessment of disinfection-by-products (DBPs)***

According to the European Union Risk Assessment (2007), during disinfection in industries and institutional areas about 1.275%[[20]](#footnote-21) of initial available chlorine will be converted in OBPs. Most of these by-products are produced during the release of the solution in the sewage system.

The proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation. About 9.1% (%OBPs) of chloroform and 2.9% (%OBPs) of trichloroacetic acid will be formed during disinfection.

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in institutional areas by professionals | 4.53 x 10-4 | **9.44 x 10-3** | 2.04 x 10-4 | **2.04 x 10-6** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 3.62 x 10-4 | **7.54 x 10-3** | 1.63 x 10-4 | **1.63 x 10-6** |
| Disinfection of milking parlour systems by professionals | 6.33 x 10-4 | **1.32 x 10-2** | 2.86 x 10-4 | **2.86 x 10-6** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-4 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in institutional areas by professionals | 4.53 x 10-5 | **3.1 x 10-4** | 2.04 x 10-5 | **1.2 x 10-1** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 3.62 x 10-5 | **2.48 x 10-4** | 1.63 x 10-5 | **9.61 x 10-2** |
| Disinfection of milking parlour systems by professionals | 6.33 x 10-5 | **4.33 x 10-4** | 2.86 x 10-5 | **1.68 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0.45 mg/kg** | | **PNECsed = 1.43 x 10-4 mg/kg** | |
| **PECsed (mg/kg)** | **PEC/PNECsed** | **PECsed (mg/kg)** | **PEC/PNECsed** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 3.72 x 10-5 | **3.1 x 10-4** | 1.72 x 10-5 | **1.2 x 10-1** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 2.97 x 10-5 | **2.48 x 10-4** | 1.38 x 10-5 | **9.61 x 10-2** |
| Disinfection of milking parlour systems by professionals | 5.2 x 10-5 | **4.33 x 10-4** | 2.41 x 10-5 | **1.68 x 10-1** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0.56 mg/kg dw** | | **PNECsoil = 4.6 x 10-3 mg/kg dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 9.69 x 10-7 | **4.2 x 10-5** | 6.98 x 10-7 | **2.47 x 10-2** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 7.74 x 10-7 | **3.35 x 10-5** | 5.59 x 10-7 | **1.98 x 10-2** |
| Disinfection of milking parlour systems by professionals | 1.35 x 10-6 | **5.86 x 10-5** | 9.77 x 10-7 | **3.46 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Groundwater***

Qualitative conclusion: As no groundwater reference value is available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to very low PECsoil values reflecting negligible emissions via STP sludge spreading and high degradation in presence of organic matter both in STP and in soil, exposure of ground water is considered to be negligible exposure.

Meta-SPC 4 (Bleach 2.6% non-professional)

***Assessment of disinfection-by-products (DBPs)***

According to the European Union Risk Assessment (2007), during disinfection in household about 1.275%[[21]](#footnote-22) of initial available chlorine will be converted in OBPs. Most of these by-products are produced during the release of the solution in the sewage system.

The proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation. About 9.1% (%OBPs) of chloroform and 2.9% (%OBPs) of trichloroacetic acid will be formed during disinfection.

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 1.33 x 10-3 | **2.77 x 10-2** | 6 x 10-4 | **6 x 10-6** |
| Disinfection of surfaces in contact with food by non-professionals | 1.67 x 10-5 | **3.47 x 10-4** | 7.51 x 10-6 | **7.51 x 10-8** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-4 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 1.33 x 10-4 | **9.11 x 10-4** | 6 x 10-5 | **3.53 x 10-1** |
| Disinfection of surfaces in contact with food by non-professionals | 1.67 x 10-6 | **1.14 x 10-6** | 7.51 x 10-7 | **4.42 x 10-3** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0.45 mg/kg** | | **PNECsed = 1.43 x 10-4 mg/kg** | |
| **PECsed (mg/kg)** | **PEC/PNECsed** | **PECsed (mg/kg)** | **PEC/PNECsed** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 1.09 x 10-4 | **9.11 x 10-4** | 4.75 x 10-5 | **3.53 x 10-1** |
| Disinfection of surfaces in contact with food by non-professionals | 1.37 x 10-6 | **1.14 x 10-6** | 5.95 x 10-7 | **4.42 x 10-3** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0.56 mg/kg dw** | | **PNECsoil = 4.6 x 10-3 mg/kg dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 2.85 x 10-6 | **1.23 x 10-4** | 3.07 x 10-7 | **1.44 x 10-2** |
| Disinfection of surfaces in contact with food by non-professionals | 3.56 x 10-8 | **1.54 x 10-6** | 3.84 x 10-9 | **1.8 x 10-4** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Groundwater***

Qualitative conclusion: As no groundwater reference value is available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to very low PECsoil values reflecting negligible emissions via STP sludge spreading and high degradation in presence of organic matter both in STP and in soil, exposure of ground water is considered to be negligible exposure.

Meta-SPC 5 (Anti-lichen professional)

***Assessment of disinfection-by-products (DBPs)***

Following the use of anti-lichen for disinfection of outdoor surfaces, disinfection-by-products are expected to be formed either in sewer system or in soil. The by-products that might be produced have not yet been studied. Based on the properties of active chlorine and the European Union Risk Assessment (2007), some assumption have been made to assess the risk linked to the by-products released from Anti-lichen.

After application and rinse of the product in a city, active chlorine will reach the sewer system. Most by-products are assumed to be formed during the transport in the sewer system. Based on the European Union Risk Assessment (2007), the fate and degradation of active chlorine could be considered quite similar to the household/industrial disinfection scenario. Thus, the following assumption has been made: following the application and the rinse of the anti-lichen product, about 1.275% of initial available chlorine is expected to be converted in OBPs. Based on the European Union Risk Assessment (2007), the proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation. About 9.1% (%OBPs) of chloroform will be formed during disinfection and 2.9% (%OBPs) of trichloroacetic acid.

Following the application and rinse of anti-lichen product in countryside, active chlorine will be emitted directly to soil. Direct exposure of soil to DBPs has not been assessed by the European Union Risk Assessment (2007) as none of the uses assessed lead to direct exposure of the soil. Moreover, active chlorine is expected to degrade rapidly in soil due to the high content of organic matter. Based on assessment report, most (≈ 99%) of the available chlorine is converted to inorganic chloride in soil. In order to present a worst-case assessment of the by-products that might be produced in soil, 1% of active chlorine was assumed to be converted into OBPs. As the distribution rate of active chlorine in OBP is not known, it was considered for the assessment that 1% Chloroform and 1% TCA could be formed.

By-products that might be formed during storm event were not assessed as the products should not be applied before storm event (see risk mitigation measure proposed in the assessment of the active substance).

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Anti-lichen used by professionals  Emission due to application and rinse of the product (city+countryside) | 6.76 x 10-4 | **1.41 x 10-2** | 2.21 x 10-4 | **2.21 x 10-6** |

**Conclusion: The requirements for acceptable risk are met according to the TGD on Risk Assessment: the PEC/ PNEC values are below the trigger value of 1 for each substances assessed.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-04 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Anti-lichen used by professionals  Emission due to application and rinse of the product (city+countryside) | 6.76 x 10-5 | **4.63 x 10-4** | 2.21 x 10-5 | **1.3 x 10-1** |

**Conclusion: The requirements for acceptable risk are met according to the TGD on Risk Assessment: the PEC/ PNEC values are below the trigger value of 1 for each substances assessed.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0,45 mg/kg** | | **PNECsed = 1,43 x 10-4 mg/kg** | |
| **PECsed (mg/kg)** | **PEC/PNECsed** | **PECsed (mg/kg)** | **PEC/PNECsed** |
| Anti-lichen used by professionals  Emission due to application and rinse of the product (city+countryside) | 5.55 x 10-5 | **4.63 x 10-4** | 1.75 x 10-5 | **1.3 x 10-1** |

**Conclusion: The requirements for acceptable risk are met according to the TGD on Risk Assessment: the PEC/ PNEC values are below the trigger value of 1 for each substances assessed.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0,56 mg/kg soil dw** | | **PNECsoil = 4,6 x 10-3 mg/kg soil dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Anti-lichen used by professionals  Emission due to application and rinse of the product (city+countryside) | 1.45 x 10-6 | **6.26 x 10-5** | 1.13 x 10-7 | **5.3 x 10-3** |

**Conclusion: The requirements for acceptable risk are met according to the TGD on Risk Assessment: the PEC/ PNEC values are below the trigger value of 1 for each substances assessed.**

***Groundwater***

As no groundwater standard values are available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to the high degradation of these substances in STP and their expected distribution in the environment, the exposure of soil is expected to be negligible and so as for the ground water.

Meta-SPC 6 (Bleach 4.8% non-professional)

***Assessment of disinfection-by-products (DBPs)***

According to the European Union Risk Assessment (2007), during disinfection in household about 1.275%[[22]](#footnote-23) of initial available chlorine will be converted in OBPs. Most of these by-products are produced during the release of the solution in the sewage system.

The proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation. About 9.1% (%OBPs) of chloroform and 2.9% (%OBPs) of trichloroacetic acid will be formed during disinfection.

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 1.27 x 10-4 | **2.65 x 10-3** | 5.75 x 10-5 | **5.75 x 10-7** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-4 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 1.27 x 10-5 | **8.7 x 10-5** | 5.75 x 10-6 | **3.38 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0.45 mg/kg** | | **PNECsed = 1.43 x 10-4 mg/kg** | |
| **PECsed (mg/kg)** | **PEC/PNECsed** | **PECsed (mg/kg)** | **PEC/PNECsed** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 1.04 x 10-5 | **8.7 x 10-5** | 4.55 x 10-6 | **3.38 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0.56 mg/kg dw** | | **PNECsoil = 4.6 x 10-3 mg/kg dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Disinfection of hard surfaces and sanitary installation by non-professionals | 2.72 x 10-7 | **1.18 x 10-5** | 2.94 x 10-8 | **1.38 x 10-3** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Groundwater***

Qualitative conclusion: As no groundwater reference value is available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to very low PECsoil values reflecting negligible emissions via STP sludge spreading and high degradation in presence of organic matter both in STP and in soil, exposure of ground water is considered to be negligible exposure.

Meta-SPC 7 (Thick Bleach professional)

***Assessment of disinfection-by-products (DBPs)***

According to the European Union Risk Assessment (2007), during disinfection in industries and institutional areas about 1.275%[[23]](#footnote-24) of initial available chlorine will be converted in OBPs. Most of these by-products are produced during the release of the solution in the sewage system.

The proportion of chloroform and trichloroacetic acid in the OBPs have been estimated by calculation. About 9.1% (%OBPs) of chloroform and 2.9% (%OBPs) of trichloroacetic acid will be formed during disinfection.

Based on this information, the PEClocal of the by-products were estimated for each uses assessed.

Exposure scenarios were performed with EUSES 2.1.2.

***Sewage treatment plant (STP)***

Overview on the calculated PEC/PNEC for sewage treatment plant (STP):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECSTP = 0.048** **mg/L** | | **PNECSTP = 100 mg/L** | |
| **PEC STP (mg/L)** | **PEC/PNEC STP** | **PEC STP (mg/L)** | **PEC/PNEC STP** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in institutional areas by professionals | 3.53 x 10-6 | **7.36 x 10-5** | 1.6 x 10-6 | **1.6 x 10-8** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 2.78 x 10-4 | **5.79 x 10-3** | 1.26 x 10-4 | **1.26 x 10-6** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Surface water***

An overview on the results of the surface water risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsw = 0.146 mg/L** | | **PNECsw = 1.7 x 10-4 mg/L** | |
| **PECsw (mg/L)** | **PEC/PNECsw** | **PECsw (mg/L)** | **PEC/PNECsw** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in institutional areas by professionals | 3.53 x 10-7 | **2.42 x 10-6** | 1.6 x 10-7 | **9.39 x 10-4** |
| Disinfection of surfaces of walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 2.78 x 10-5 | **1.9 x 10-4** | 1.26 x 10-5 | **7.4 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Sediment***

An overview on the results of the sediment risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsed = 0.45 mg/kg** | | **PNECsed = 1.43 x 10-4 mg/kg** | |
| **PECsed (mg/kg)** | **PEC/PNECsed** | **PECsed (mg/kg)** | **PEC/PNECsed** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 2.9 x 10-7 | **2.42 x 10-6** | 1.34 x 10-7 | **9.39 x 10-4** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 2.28 x 10-5 | **1.9 x 10-4** | 1.06 x 10-5 | **7.4 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Terrestrial compartment***

An overview on the results of the soil risk assessment for chloroform and trichloroacetic acid is provided:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Chloroform** | | **Trichloroacetic acid** | |
| **Exposure scenario** | **PNECsoil = 0.56 mg/kg dw** | | **PNECsoil = 4.6 x 10-3 mg/kg dw** | |
| **PECsoil (mg/kg dw)** | **PEC/PNECsoil** | **PECsoil (mg/kg dw)** | **PEC/PNECsoil** |
| Disinfection of lavatory, surfaces, walls, floors, tools, and other objects in institutional areas by professionals | 7.56 x 10-9 | **3.28 x 10-7** | 5.46 x 10-9 | **1.94 x 10-4** |
| Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals | 5.95 x 10-7 | **2.58 x 10-5** | 4.31 x 10-7 | **1.53 x 10-2** |

**Conclusion: Risks are acceptable according to the TGD on Risk Assessment: the PEC/PNEC ratios are below the trigger value of 1 for each by-product.**

***Groundwater***

Qualitative conclusion: As no groundwater reference value is available for chloroform and trichloroacetic acid, groundwater assessments were not performed. Nevertheless due to very low PECsoil values reflecting negligible emissions via STP sludge spreading and high degradation in presence of organic matter both in STP and in soil, exposure of ground water is considered to be negligible exposure.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-3)
3. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-4)
4. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-5)
5. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-6)
6. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-7)
7. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-8)
8. Assessment report, January 2017 – Active chlorine released from sodium hypochlorite. Italy [↑](#footnote-ref-9)
9. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-10)
10. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-11)
11. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-12)
12. WHO, 2005. Chlorite and chlorate in drinking-water. Background document for development of WHO Guidelines for drinking-water quality. WHO/SDE/WSH/05.08/86 [↑](#footnote-ref-13)
13. EC, 2020 : Directive (EU) 2020/2184 of the european parliament and of the council of 16 December 2020 on the quality of water intended for human consumption. [↑](#footnote-ref-14)
14. Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017 [↑](#footnote-ref-15)
15. https://ec.europa.eu/food/plant/pesticides/chlorate\_en [↑](#footnote-ref-16)
16. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-17)
17. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-18)
18. European Risk Assessment (2007) has considered that 1,5% of OBPs were converted from active chlorine during laundry disinfection and disinfection of surfaces. In order to present a more realistic case, only the OBPs due to disinfection of surface will be taken into account for the assessment. This type of application represents 85% of the market, thus it has been estimated that 85% of the 1,5% OBPs found in the effluent following disinfection in institutional areas and industries were due to surface disinfection. [↑](#footnote-ref-19)
19. European Risk Assessment (2007) has considered that 1.5% of OBPs were converted from active chlorine during laundry disinfection and disinfection of surfaces. In order to present a more realistic case, only the OBPs due to disinfection of surface will be taken into account for the assessment. This type of application represents 85% of the market, thus it has been estimated that 85% of the 1.5% OBPs found in the effluent following disinfection in institutional areas and industries were due to surface disinfection. [↑](#footnote-ref-20)
20. European Risk Assessment (2007) has considered that 1.5% of OBPs were converted from active chlorine during laundry disinfection and disinfection of surfaces. In order to present a more realistic case, only the OBPs due to disinfection of surface will be taken into account for the assessment. This type of application represents 85% of the market, thus it has been estimated that 85% of the 1.5% OBPs found in the effluent following disinfection in institutional areas and industries were due to surface disinfection. [↑](#footnote-ref-21)
21. European Risk Assessment (2007) has considered that 1.5% of OBPs were converted from active chlorine during laundry disinfection and disinfection of surfaces. In order to present a more realistic case, only the OBPs due to disinfection of surface will be taken into account for the assessment. This type of application represents 85% of the market, thus it has been estimated that 85% of the 1.5% OBPs found in the effluent following disinfection in institutional areas and industries were due to surface disinfection. [↑](#footnote-ref-22)
22. European Risk Assessment (2007) has considered that 1.5% of OBPs were converted from active chlorine during laundry disinfection and disinfection of surfaces. In order to present a more realistic case, only the OBPs due to disinfection of surface will be taken into account for the assessment. This type of application represents 85% of the market, thus it has been estimated that 85% of the 1.5% OBPs found in the effluent following disinfection in institutional areas and industries were due to surface disinfection. [↑](#footnote-ref-23)
23. European Risk Assessment (2007) has considered that 1.5% of OBPs were converted from active chlorine during laundry disinfection and disinfection of surfaces. In order to present a more realistic case, only the OBPs due to disinfection of surface will be taken into account for the assessment. This type of application represents 85% of the market, thus it has been estimated that 85% of the 1.5% OBPs found in the effluent following disinfection in institutional areas and industries were due to surface disinfection. [↑](#footnote-ref-24)